
EXHIBIT R

T4718 ALLEN TRANSLATION SERVICE
Translated from French 1

PROLENE® MESH
Polypropylene

Technical File

Strictly Confidential Document

July 1995

ETHNOR S.A.

ETHICON FRANCE

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II. CONFORMITY WITH
ESSENTIAL REQUIREMENTS

II.1. GENERAL REQUIREMENTS

1. "The devices are to be designed and manufactured in such a way that their use does not compromise the clinical state and the safety of the patients nor the safety and health of the users or, where applicable, of other persons, when they are used under the conditions and for the purposes anticipated, it being understood that the possible risks linked to their use constitute risks that are acceptable with regard to the benefit brought to the patient and are compatible with a high level of protection of health and safety."

The PROLENE® Mesh manufactured by Ethnor SA is inspected in conformity with the requirements of the quality system ISO 9001/EN 29001 and NF EN 46001 applied according to the NF EN 724 guide.

- ⇒ ISO 9001 - Quality systems - Model for quality assurance in design/development, production, installation and servicing after sale.
- ⇒ NF EN 46001 - Quality systems - Medical devices - Specific requirements related to the application of EN 29001.
- ⇒ NF EN 724 - Guide for application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices.

The publications relative to the clinical use of PROLENE® Mesh are added in Section VI.

2. "The solutions chosen by the manufacturer in the design and construction of the devices must be in accordance with the principles of integration of safety, taking into account the generally recognized state of the art."

The safety principles used in the original design and the construction of the device were those required by the FDA when it was first developed in the United States. The manufacturer by Ethnor SA was originally in conformity with the requirements of the Guide to good manufacturing practices for sterile medical materials and surgical products. It is now in conformity with EN 29001 and EN 46001 as specified in 1, above.

3. "The devices must attain the performances assigned to them by the manufacturer and should be designed, manufactured and packaged so as to be capable of fulfilling one or several of the functions referred to in Article 1, paragraph 2, point a) and such as are specified by the manufacturer."

PROLENE® Mesh can be used in humans and conforms to the definition of a medical device as in paragraph 2, point a) of the first Article of the EEC Directive 93/42. The performances assigned by the manufacturer are shown in the instructions for use. The indications, contraindications, warnings and precautions for use are also recorded.

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4. "The characteristics and performances referred to in points 1, 2 and 3 must not be changed in such a way as to compromise the clinical state and the safety of the patients and, where applicable, other persons for the duration of the life of the devices following the indications of the manufacturer when these devices are subjected to the stresses that can arise under normal conditions of use."

PROLENE® Mesh is a single-use device. The life of the product is equivalent to the duration of its implantation in the organism. The studies reported in Section VII show that PROLENE® Mesh is well tolerated in the organism.

5. "The devices must be designed, manufactured and packaged in such a way that their characteristics and their performances in view of their intended use are not changed during storage and transportation, bearing in mind the instructions and information provided by the manufacturer."

The storage time for PROLENE® Mesh is five years if the device is stored at a temperature below 25 degrees Celsius, away from humidity and direct heat. Stability studies show that the characteristics and performances are unchanged under these conditions until it is used. The shelf life of the device is shown on the wrapping. The instructions for use state that the device is not to be used after the expiration date.

6. "Any secondary, undesirable effect must constitute an acceptable risk with respect to the performances ascribed."

When PROLENE® Mesh is used, a slight inflammatory reaction can be observed. This is due in part to the natural healing process.

Warnings and precautions for use of the device are specified in the instructions for use.

**II.2. REQUIREMENTS RELATED TO DESIGN
AND CONSTRUCTION**

7. Chemical, physical and biological properties.

7.1. The devices must be designed and manufactured so as to assure the characteristics and performances referred to in Section 1 "General requirements." Particular attention must be paid to:

- the choice of materials used, especially as far as toxicity and, if applicable, the flammability are concerned.
- the mutual compatibility of the materials used, the tissues and biological cells, and also the body fluids, taking into account the intended use of the device.

PROLENE® Mesh is composed of non-absorbable filaments of polypropylene, the composition of which is identical to that of PROLENE® suture threads. The biocompatibility studies presented are therefore those carried out on PROLENE® sutures.

PROLENE® Mesh has been used since 1973. The bibliographical references relating to PROLENE® in the mesh form give a selection of various surgical uses of this device and demonstrate that it can be used in complete safety.

⇒ In vitro cytotoxicity

- Report of ETHICON Limited Study No. 39/93, 04/30/93: no cytotoxicity was demonstrated.
- PTS accession No. 92-1411: no toxic effect was demonstrated.

⇒ In Vivo cytotoxicity

- Biological evaluation of PROLENE® Mesh: ERF Accession No. 73-130. After a 3-day implantation, a minor edematous reaction is observed with minimal proliferation of fibroblasts. The proliferation of collagen fibers is classically observed after 28 days of implantation. A minor foreign body reaction is noted.
- Study of tissue reactions to polypropylene thread (PROLENE®): Report of ETHICON Limited Study No. 38/82, 09/27/82. The tissue reactions observed between day 1 and day 120 are very minor and are confirmed long-term.
- Report of ETHICON Limited Study, 10/14/65: ocular implantation of PROLENE® suture in the rabbit. The polypropylene thread maintained its properties to term and appeared to be inert.

⇒ Carcinogenicity

- Report of ETHICON Limited Study 10/14/65: observation after a 3-month implantation in the dog and a 24-month implantation in the rat. No carcinogenic effect was demonstrated.

(COPIES OF STUDIES: see Section VI)

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7.2. The devices must be designed, manufactured and packaged so as to minimize the risk presented by contaminants and residues for personnel involved in transportation, storage and use as well as for the patients, in conformity with the intended use of the product. Particular attention must be paid to the tissues exposed, as well as to the duration and frequency of exposure.

PROLENE® Mesh is sterilized with ethylene oxide. The amount of ethylene oxide residues resulting from the sterilization cycle has been determined and is substantially lower (< 1 ppm) than the amount considered acceptable in the norm ISO/DIS 10993-7, "Biological evaluation of medical devices - Residues from sterilization with ethylene oxide."

7.3. The devices must be designed and manufactured so that they can be used in complete safety with the materials, substances and gases with which they enter into contact in the course of their normal use or during routine procedures; if the devices are intended for the administration of medications, they must be designed and manufactured so as to be compatible with the medications involved, in conformity with the provisions and restrictions applicable to the latter, and so that their performance is maintained in conformity with their intended use.

No publication to date has mentioned problems associated with interactions between PROLENE® Mesh and other materials, substances or gases. Under normal conditions of use, PROLENE® Mesh thus does not present this type of interaction risk.

7.4. When a device incorporates as an integral part a substance which, if used separately, may be considered a medication as defined by Article 1 of the Directive 65/65/EEC, and which can act on the human body by an action secondary to that of the device, the quality and usefulness of this substance must be verified, taking into consideration the intended use of the device, by analogy with the appropriate methods contained in the Directive 75/318/EEC.

Not applicable.

7.5. The devices must be designed and manufactured so as to reduce to a minimum the risks arising from substances escaping from the device.

Not applicable.

7.6. The devices must be designed and manufactured so as to minimize as much as possible the risks due to unintentional passage of substances into the device, taking into account the device and the nature of the environment in which it is designed to be used.

Not applicable.

8. Infection and microbial contamination

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8.1. "The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as much as possible the risk of infection for the patient, the user and third parties. The design must allow easy handling and, as far as necessary, minimize the contamination of the device by the patient or vice versa in the course of use."

The risk of infection for the patient is eliminated by the following means:

- => The manufacture is carried out in a monitored and periodically checked environment.
- => The initial contamination of the product is measured in order to check the quality of the manufacturing environment.
- => The product is sterilized with ethylene oxide. [orig. erroneously states "...sterilized by irradiation."]

Checking of the environment

The microbial contamination of work sites and the atmosphere is regularly monitored. Corrective measures are undertaken if the results are higher than the predetermined values.

Checking of initial contamination of the product

The bioburden is measured regularly on samples taken at random immediately before sterilization.

Sterilization of the product

The product is sterilized with ethylene oxide [orig. erroneously states "... sterilized by irradiation."] according to a procedure validated and checked in conformity with EN 550 "Sterilization of medical devices. Method of validation and routine checking of sterilization with ethylene oxide." The sterility assurance level is 10^{-6} and the product is labelled "Sterile" in conformity with the requirements of EN 556 "Sterilization of medical devices. Requirements for medical devices labelled Sterile."

8.2. "Tissues of animal origin must come from animals that have been subjected to veterinary inspections and monitoring measures adapted to the use for which the tissues are intended."

Not applicable.

8.3. "Devices which are supplied in the sterile state must be designed, manufactured and packaged in non-reusable packaging and/or according to appropriate procedures so that they are sterile at the time they are put on the market and that under the conditions for storage and transportation laid down they maintain this quality until the protective packaging assuring sterilization is damaged or opened."

The following measures contribute to the assurance of the fulfillment of the above requirements.

8.3.1. Validation and type of wrapping.

The product is packaged in a non-reusable, heat-sealed wrapping composed of a blister closed with a sheet of Tyvek®.

Validation includes the evaluation of the following properties:

- => Compatibility of packaging and product
- => The compatibility of the packaging and the sterilization procedure. This point is included in the validation of the sterilization process.
- => The microbiological barrier properties of the packaging
- => The integrity of the seal.

The various materials used have been demonstrated to be in conformity with the preceding requirements.

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8.3.2. Stability data and storage recommendations

Various studies have been carried out at ambient temperature (not controlled) and for a period of five years to make sure of the stability of the product and of its packaging. No deterioration of the packaging was observed and the product remained sterile and retained its physical properties, which proves the effectiveness of the packaging materials and of the sealing process. The storage conditions recommended as a result of these studies are: storage below 25 degrees C, away from humidity and heat. The shelf life is five years. The storage conditions are shown in the instructions for use. The expiration date is indicated on each package and on each box.

8.4. "Devices which are supplied in the sterile state must have been manufactured and sterilized by an appropriate, validated method."

8.4.1. Sterilization procedures

PROLENE® Mesh is sterilized with ethylene oxide - see Section IV.

8.4.2. Validation procedures

Validations of the ethylene oxide sterilization procedure were carried out according to ETHNOR SA internal procedures, applying procedures of Johnson & Johnson.

Future validations will be carried out in conformity with the requirements of EN 550 "Sterilization of medical devices. Validation and routine control of sterilization with ethylene oxide." See Section IV.4.2.

8.5. "Devices that are intended for sterilization must be manufactured under conditions satisfying the appropriate controls (for example, environmental control)."

Not applicable. The devices manufactured by ETHNOR are offered in the sterile state.

8.6. "Systems of packaging intended for non-sterile devices must be such as to preserve the product without deterioration at the level of cleanliness provided for and, if they are intended to be sterilized before their use, to minimize the risk of microbial contamination."

Not applicable. The devices manufactured by ETHNOR are offered in the sterile state.

9. Properties relating to manufacture and the environment

9.1. The precautions and warnings relating to the use of PROLENE® Mesh are given in the instructions for use.

9.2. PROLENE® Mesh is offered in several sizes. The choice of the most appropriate size falls to the surgeon.

Polypropylene is a material that must not be used in direct contact with a heat source that could cause melting.

Aging studies and stability studies carried out before product market availability indicated that risks arising from the aging of the materials are not a factor. The expiration period of these devices is set at 5 years. The expiration date is inscribed on each package box and on each wrapping.

10. Devices with a measurement function.

Not applicable.

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11. Protection against radiation.

Not applicable.

12. Requirements for medical devices connected to an energy source or equipped with such a source.

Not applicable.

13. Information provided by the manufacturer.

13.1. "Each device must be accompanied by the information required for it to be able to be used in complete safety and to permit identification of the manufacturer, taking into account the training and knowledge of the potential users.

This information comprises the indications in the instructions for use.

To the extent possible and appropriate, the information required for the use of the device in complete safety must be on the device itself and/or on the wrapping of each unit or, where appropriate, on the commercial wrapping. If it is not possible to wrap each unit separately, the information must be on a sheet accompanying one or more devices.

The packaging of each device must contain instructions for use. An exception is made for devices of classes I and IIa, if they can be used completely safely without the aid of such instructions."

The labelling of the primary wrapping or of the box is in conformity with the requirements of the European Standards on Labelling prEN 1041 "Information provided by the manufacturer with medical devices." They correspond to Sections 13.1 to 13.5 of Appendix I of the Directive relating to medical devices. The symbols used are in conformity with prEN 980 "Graphic symbols used in the labelling of medical devices." The key to these symbols is repeated in the instructions for use.

PROLENE® Mesh is a Class IIb device in conformity with Rule 8 of Appendix IX. Instructions for use are included in each unit intended for sale. The instructions are reproduced in Section IX and are in conformity with the requirements of the European Standards on Labelling and with Section 13.6 of Appendix I when appropriate.

VI. BIOLOGICAL STUDIES

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VI.1. CYTOTOXICITY STUDIES

- Report of study by ETHICON Limited, No. 39/93
PTS ACCESSION No. 92-1411 of 1/25/93, attached
- ERF Accession No. 73-130
- Report of study by ETHICON Limited, No. 38-82
- Report of study by ETHICON Limited, 10/14/65.

06003

(Ethicon Limited Report No. 39/93, 30.4.93)

Summary

Samples of metric 1.0 sutures were examined for in-vitro cytotoxicity using the Agar overlay and Extraction/Neutral Red Uptake tests.

Sample Preparation

- Sutures were cut to 1 cm lengths for the Agar Overlay Test. Extracts were prepared in serum containing growth medium for 24 hours at 37 deg C for the Neutral Red Uptake test. Extract strength was 1.0 cm²/ml.

Cell Line

- NCTC Clone L929 Mouse Fibroblasts Passage No. 608-610.

Medium

- Minimum Essential Medium (MEM) with Earle's Salts, 5% foetal calf serum, 1 mM glutamine, 1% non-essential amino acids, 2.2 g/litre NaHCO₃.

Procedure Agar Overlay

- Samples were added directly to the cell monolayers in the Agar Overlay system.

Results Agar Overlay

- No zone of cytotoxicity was found. Cells were stained and intact.

Procedure Neutral Red Uptake

- Extracts and dilutions (50%) were exposed to cells for 24 hours in 96 well microplates. Optical density was read at 540 nm on a microplate reader.

Results Neutral Red Uptake

- Little or no reduction in Neutral Red Uptake.

93-0301

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ETHICON, Inc.

a Johnson & Johnson company

Department of
Pathology, Toxicology & Surgery



06004

JAN 25 1993

K. Purcell (Cornelia)

cc: S. H. Liu
RDCF

IN VITRO CYTOTOXICITY:

PROLENE POLYPROPYLENE MESH:

LOT #D356 2980 - NORMAL PRODUCTION,

SCoured AND W/ETHASEW WAX AS A LUBRICANT;

LOT #D42990 - NOT SCoured AND

W/PARAFFIN OIL AS A LUBRICANT;

LOT #D2949 - SCoured AND

W/PARAFFIN OIL AS A LUBRICANT

PTS ACCESSION NO.

92-1411

PROJECT NO. 99999

The above-captioned samples, and extracts thereof, were non-cytotoxic when tested in the agar overlay assay. The results of these studies are summarized in the attached copies of the final reports issued by North American Science Associates, Inc. on January 7, 1993.

Lia Martini 1/25/93
L. Martini, B.S.
Study Coordinator
Associate Scientist, Toxicology

J. F. Dooley 1/25/93
J. F. Dooley, Ph.D.
Principal Scientist, Toxicology

Attachment
G:\92-1411R.LMH

ETHICON INC.

JAN 26 1993

RD-CENTRAL FILE

CONFIDENTIAL

SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

ETH.MESH.06398827



*World Leader in Testing Services
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P.O. NO. 259155

ETHICON, INCORPORATED
P.O. BOX 151
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LOT NO. 92-1411

ATTN: LISA MARTINI

06005

CYTOTOXICITY - AGAROSE OVERLAY

Test Article: Prolene polypropylene mesh Lot #D356 2980; Normal Production, scoured and with Ethasew Wax

Test Article Description: Mesh - 1 sq. cm piece

Procedure: A monolayer of L-929 mouse fibroblast cells was grown to confluence and overlaid with Minimum Essential Medium supplemented with serum, antibiotics, neutral red, and agarose. The test article, a 0.5 cm x 0.5 cm piece of P-11102 as a positive control, and a 1.0 cm length piece of USP negative control were placed on the solidified overlay surface. Following incubation for 24 hours, the culture was macroscopically examined for evidence of cell decolorization to determine the zone of cell lysis. Any decolorized zone present was examined microscopically to confirm cell lysis.

	<u>Score</u>	<u>Observations</u>
	N (Nontoxic)	No change in cell morphology in proximity to test sample.
	T (Toxic)	Death and/or degeneration of cells directly beneath the area of test sample and possibly also within a zone extended beyond the test sample. Where a zone of lysis was observed, the distance from the edge of the sample to the edge of the zone was measured and reported in millimeters (mm).

Results:	<u>Test/Control Articles</u>	<u>Score</u>	<u>Zone of Lysis (mm)</u>
	Test Article Results	N	0
	USP Negative Control	N	0
	Positive Control: P-11102	T	9

Conclusion: The above test article was nontoxic for L-929 mouse fibroblast cells under the above described test parameters.

Comments: Not Applicable.

Date Prepared: 1-5-93

Date Terminated: 1-6-93

lms
mrm

Completed 1-7-93 Tech LMN/JMT

Approved

MG030-110

CONFIDENTIAL

SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

ETH.MESH.06398828



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LOT NO. 92-1411

ATTN: LISA MARTINI

06006

CYTOTOXICITY - AGAROSE OVERLAY WITH EXTRACTION

Test Article: Prolene polypropylene mesh Lot #D356 2980; Normal Production, scoured and with Ethasew Wax

Procedure: The test article was prepared by extracting 60 sq. cm in 20 ml of 0.9% SC in an extraction vessel at 37°C for 24 hour(s). A monolayer of L-929 mouse fibroblast cells was grown to confluence and overlaid with Minimum Essential Medium supplemented with serum, antibiotics, neutral red, and agarose. A 0.1 ml portion of the test article extract on a filter paper disc was placed on the solidified overlay surface. Also placed on the agarose surface was: (a) a filter paper disc saturated with 0.1 ml 0.9% SC as a negative control, (b) a 1.0 cm length piece of USP negative control, and (c) a 0.5 cm x 0.5 cm piece of P-11102 as a positive control. Following incubation for 24 hours, the culture was macroscopically examined for evidence of cell decolorization to determine the zone of cell lysis. Any decolorized zone present was examined microscopically to confirm cell degeneration or lysis.

<u>Score</u>	<u>Observations</u>
N (Nontoxic)	No change in cell morphology in proximity to test article.
T (Toxic)	Death and/or degeneration of cells directly beneath the area of test sample and possibly also within a zone extended beyond the test sample. Where a zone of lysis was observed, the distance from the edge of the sample to the edge of the zone was measured and reported in millimeters (mm).

<u>Results:</u>	<u>Test/Control Articles</u>	<u>Score</u>	<u>Zone of Lysis (mm)</u>
	Test Article Results	N	0
	USP Negative Control	N	0
	Filter Disc Control: 0.9% SC	N	0
	Positive Control: P-11102	T	8

Conclusion: The above test article was nontoxic for L-929 mouse fibroblast cells under the above described test parameters.

Comments: Not Applicable.
Date Prepared: 1-4-93 Date Terminated: 1-6-93

Ims
MMR

Completed 1-7-93 Tech. KSH/SDR/LMN

Approved Jamie M. Price

MG030-130



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ATTN: LISA MARTINI

06007

CYTOTOXICITY - AGAROSE OVERLAY

Test Article: Prolene polypropylene mesh Lot #D42990, not scoured, with Parafin oil as lubricant

Test Article Description: Mesh - 1 sq. cm piece

Procedure: A monolayer of L-929 mouse fibroblast cells was grown to confluence and overlaid with Minimum Essential Medium supplemented with serum, antibiotics, neutral red, and agarose. The test article, a 0.5 cm x 0.5 cm piece of P-11102 as a positive control, and a 1.0 cm length piece of USP negative control were placed on the solidified overlay surface. Following incubation for 24 hours, the culture was macroscopically examined for evidence of cell decolorization to determine the zone of cell lysis. Any decolorized zone present was examined microscopically to confirm cell lysis.

<u>Score</u>	<u>Observations</u>
N (Nontoxic)	No change in cell morphology in proximity to test sample.
T (Toxic)	Death and/or degeneration of cells directly beneath the area of test sample and possibly also within a zone extended beyond the test sample. Where a zone of lysis was observed, the distance from the edge of the sample to the edge of the zone was measured and reported in millimeters (mm).

Results:	<u>Test/Control Articles</u>	<u>Score</u>	<u>Zone of Lysis (mm)</u>
	Test Article Results	N	0
	USP Negative Control	N	0
	Positive Control: P-11102	T	9

Conclusion: The above test article was nontoxic for L-929 mouse fibroblast cells under the above described test parameters.

Comments: Not Applicable.
Date Prepared: 1-5-93 Date Terminated: 1-6-93

Ims Completed 1-7-93 Tech.LMN/JMT Approved Lisa M. Joud



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LOT NO. 92-1411

ATTN: LISA MARTINI

06008

CYTOTOXICITY - AGAROSE OVERLAY WITH EXTRACTION

Test Article: Prolene polypropylene mesh Lot #D42990, not scoured, with Parafin oil as lubricant

Procedure: The test article was prepared by extracting 60 sq. cm in 20 ml of 0.9% SC in an extraction vessel at 37°C for 24 hour(s). A monolayer of L-929 mouse fibroblast cells was grown to confluence and overlaid with Minimum Essential Medium supplemented with serum, antibiotics, neutral red, and agarose. A 0.1 ml portion of the test article extract on a filter paper disc was placed on the solidified overlay surface. Also placed on the agarose surface was: (a) a filter paper disc saturated with 0.1 ml 0.9% SC as a negative control, (b) a 1.0 cm length piece of USP negative control, and (c) a 0.5 cm x 0.5 cm piece of P-11102 as a positive control. Following incubation for 24 hours, the culture was macroscopically examined for evidence of cell decolorization to determine the zone of cell lysis. Any decolorized zone present was examined microscopically to confirm cell degeneration or lysis.

	<u>Score</u>	<u>Observations</u>
N (Nontoxic)		No change in cell morphology in proximity to test article.
T (Toxic)		Death and/or degeneration of cells directly beneath the area of test sample and possibly also within a zone extended beyond the test sample. Where a zone of lysis was observed, the distance from the edge of the sample to the edge of the zone was measured and reported in millimeters (mm).

<u>Results:</u>	<u>Test/Control Articles</u>	<u>Score</u>	<u>Zone of Lysis (mm)</u>
	Test Article Results	N	0
	USP Negative Control	N	0
	Filter Disc Control: 0.9% SC	N	0
	Positive Control: P-11102	T	8

Conclusion: The above test article was nontoxic for L-929 mouse fibroblast cells under the above described test parameters.

Comments: Not Applicable.

Date Prepared: 1-4-93

Date Terminated: 1-6-93

lms Completed 1-7-93 Tech.KSH/SDR/LMN

Approved



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LOT NO. 92-1411

06009

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ATTN: LISA MARTINI

CYTOTOXICITY - AGAROSE OVERLAY WITH EXTRACTION

Test Article: Prolene polypropylene mesh, Lot #D2949; scoured & with Parafin oil as lubricant

Procedure: The test article was prepared by extracting 60 sq. cm in 20 ml of 0.9% SC in an extraction vessel at 37°C for 24 hour(s). A monolayer of L-929 mouse fibroblast cells was grown to confluence and overlaid with Minimum Essential Medium supplemented with serum, antibiotics, neutral red, and agarose. A 0.1 ml portion of the test article extract on a filter paper disc was placed on the solidified overlay surface. Also placed on the agarose surface was: (a) a filter paper disc saturated with 0.1 ml 0.9% SC as a negative control, (b) a 1.0 cm length piece of USP negative control, and (c) a 0.5 cm x 0.5 cm piece of P-11102 as a positive control. Following incubation for 24 hours, the culture was macroscopically examined for evidence of cell decolorization to determine the zone of cell lysis. Any decolorized zone present was examined microscopically to confirm cell degeneration or lysis.

<u>Score</u>	<u>Observations</u>
N (Nontoxic)	No change in cell morphology in proximity to test article.
T (Toxic)	Death and/or degeneration of cells directly beneath the area of test sample and possibly also within a zone extended beyond the test sample. Where a zone of lysis was observed, the distance from the edge of the sample to the edge of the zone was measured and reported in millimeters (mm).

<u>Results:</u>	<u>Test/Control Articles</u>	<u>Score</u>	<u>Zone of Lysis (mm)</u>
	Test Article Results	N	0
	USP Negative Control	N	0
	Filter Disc Control: 0.9% SC	N	0
	Positive Control: P-11102	T	10

Conclusion: The above test article was nontoxic for L-929 mouse fibroblast cells under the above described test parameters.

Comments: Not Applicable.

Date Prepared: 1-4-93

Date Terminated: 1-6-93

lms
A.M.A.

Completed 1-7-93 Tech.KSH/SDR/LMN

Approved Jennie M. French
11 Mutual direction

MG030-130



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P.O. NO. 259155

ETHICON, INCORPORATED
P.O. BOX 151
SOMERVILLE, NJ 08876

LOT NO. 92-1411

ATTN: LISA MARTINI

06010

CYTOTOXICITY - AGAROSE OVERLAY

Test Article: Prolene polypropylene mesh, Lot #D2949; scoured & with Parafin oil as lubricant

Test Article Description: Mesh - 1 sq. cm piece

Procedure: A monolayer of L-929 mouse fibroblast cells was grown to confluence and overlaid with Minimum Essential Medium supplemented with serum, antibiotics, neutral red, and agarose. The test article, a 0.5 cm x 0.5 cm piece of P-11102 as a positive control, and a 1.0 cm length piece of USP negative control were placed on the solidified overlay surface. Following incubation for 24 hours, the culture was macroscopically examined for evidence of cell decolorization to determine the zone of cell lysis. Any decolorized zone present was examined microscopically to confirm cell lysis.

<u>Score</u>	<u>Observations</u>
N (Nontoxic)	No change in cell morphology in proximity to test sample.
T (Toxic)	Death and/or degeneration of cells directly beneath the area of test sample and possibly also within a zone extended beyond the test sample. Where a zone of lysis was observed, the distance from the edge of the sample to the edge of the zone was measured and reported in millimeters (mm).

<u>Results:</u>	<u>Test/Control Articles</u>	<u>Score</u>	<u>Zone of Lysis (mm)</u>
	Test Article Results	N	0
	USP Negative Control	N	0

Positive Control: P-11102 T 8

Conclusion: The above test article was nontoxic for L-929 mouse fibroblast cells under the above described test parameters.

Comments: Not Applicable.
Date Prepared: 1-5-93 **Date Terminated:** 1-6-93

1ms
M100

Completed 1-7-93 Tech.LMN/JMT

Approved

Xenia M. French MG030-110

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ETH.MESH.06398833

06011

PLEASE USE YELLOW HIGHLIGHTER PEN TO HIGHLIGHT WORDSERF Acc. No. 92-1411**1) ADDITIONAL SAMPLE DESCRIPTION**
(include only if not in title)

Form:
 Mesh Mono
 Staple Braid
 Clip Dyed
 Absorbable Undyed
 Adhesive Coating
 Film Size _____
 Coupler Other _____
 Non-absorbable

Test system:

Rat	Cell culture
House	Guinea pig
Rabbit	Pig
Dog	Goat
Human	Other _____

Photography:

Gross photo	Video
Micro photo	SEM photo
TEM photo	Other _____

2) ADDITIONAL STUDY DESCRIPTIONStudy Type:

Tissue reaction	Demonstration
Porportion	Sales School
Leaking strength	Laser
Function	GLP
Developmental	Ex vivo
Product Service Review	In vitro
Product Inquiry Affiliate	Dept. objective
Veterinary inquiry	Training study
Pilot	Competitive test
Cancer	Comparative
Allergen	Patency
Intracutcut Irritat	Stability
Mutagen	Hinge strength
Pyrogen	Tensiometry
Acute tox	Photomicrography
Gross TR	
Other	CYTOTOXICITY

3) ADDITIONAL HISTOLOGY DESCRIPTION:

Embed:
 GMA Ground section
 Frozen section Other _____

Special Stains:

ORO	Iron
Silver	Calcium
Trichrome	Giems
PAS	Gram
PTAH	Immunohistochem
VG	Other _____

Slides, no slides, histopath report**4) SURGICAL DESCRIPTION:**

Anastomosis vascular	Keratotomy
Anastomosis	Laparotomy
Colotomy	Lobectomy
Craniotomy	Splenectomy
Cystotomy	Thoracotomy
Gastrotomy	Ligation
Ovariohysterectomy	Other _____

5) MISCELLANEOUS:

Biochem analysis	Other _____
Clinical pathology	Other _____
Radiography	Other _____
Biomechanics test	

Implant Site:

IH	Stomach
Eye	Genital tract
Vascular	Lung
IP	Skin
IV	Small intestine
Intradermal	Spleen
Dura	Colon
Urinary bladder	Bone
	Other _____

Implant period-days: List

633A/cal

73-2675
TECHNICAL REPORT
To: Mr. E. A. Block
Subject: PROLENE* MESH - BIOLOGICAL EVALUATION IN RABBITS
(3, 28 days)



06012

cc: Dr. C. Artandi
Dr. P. V. Buday
Dr. J. P. Jones
Dr. R. L. Krone
Mr. T. N. Salth
RDCF

ERF ACCESSION NO.

73-130 ✓
Project No. 20901

SUMMARY

PROLENE* mesh was implanted subcutaneously in the abdominal wall of twelve albino rabbits for 3 and 28 days to determine its tissue response.

A minimal to slight acute response consisting of transient edema, hemorrhage or hyperemia, and inflammatory cell infiltration was elicited by PROLENE mesh. This reaction was supplanted by moderate fibrous encapsulation of mesh filaments and connective tissue formation in spaces between filaments after one month of implantation.

The reactions to PROLENE mesh were similar in type and extent to the response elicited by Marlex mesh implanted as a control.

ETHICON, INC.

AUG 27 1973

RD-Central File

Reported By

Dr. M. H. Wykoff
Dr. J. A. Williams

Approved By

Dr. Peter H. Craig

rb

*Trademark

06013

Materials:

<u>ERF No.</u>	<u>Lot</u>	<u>Description</u>	<u>Sterility No.**</u>
1	1131-110-3	PROLENE* mesh 5 cm x 2 cm	F158KB1
2	1131-110-2	Marlex mesh 5 cm x 2 cm	F158KB1

** Ethylene oxide sterilized.

Procedures:

Six male and six female albino rabbits were anesthetized and shaved from the xiphoid cartilage to the pubis. The skin was incised bilaterally 2 cm from the midline at the level of the umbilicus. The skin was then separated from the subcutaneous fascia so that a pocket was formed to accept a mesh sample. A sample of either PROLENE or Marlex mesh 2 x 5 cm was then inserted into this pocket and the skin closed with ETHILON* sutures. Both Marlex and PROLENE meshes were placed an equal number of times on the left and right sides of rabbits of each sex.

At necropsy implant sites were examined for gross lesions. The implant along with overlying skin and underlying abdominal muscle was removed and fixed in buffered formalin for histologic preparation. From each site, two sections stained with hematoxylin and eosin were prepared and examined for inflammatory response and connective tissue proliferation in implants.

Results:Gross Observations at Necropsy:

No untoward abnormality was noted at necropsy for either the PROLENE mesh or Marlex mesh implanted as a control. Minimal hemorrhage was noted in three PROLENE mesh and two Marlex mesh sites after three days. Minimal or slight edema was observed in three implant sites for each material. No observable gross changes were found for either mesh material at 28 days post implantation.

Histopathologic Observations:

Tissue response to PROLENE mesh implanted subcutaneously in the abdominal wall of rabbits was graded minimal or slight at 3 and 28 days post implantation in all but two sites. The responses elicited by PROLENE mesh were similar in type and extent to

06014

Marlex mesh implanted as a control. Details of responses in individual animals are set forth in Tables 1-4.

At 3 days post implantation minimal erythrocyte extravasation, mild edema, slight vascular proliferation, scattered macrophages and a few heterophils were typical of responses present around PROLENET* mesh implants. Proliferation of fibroblasts was minimal at this interval. Some difficulty was encountered in retaining morphologic relationship of implant to adjacent tissues at the early interval.

Collagenous fiber proliferation around PROLENE mesh filaments typified the response noted at 28 days post implantation. Collagenous fibers also extended between filaments filling in mesh spaces. A mild foreign body giant cell reaction was noted, but was not different from that seen associated with Marlex implants. Neither was fibrous tissue proliferation around Marlex implants more extensive than noted around PROLENE mesh implants.

Pyogenic response in two implant sites, Marlex rabbit #1 at 3 days and PROLENE mesh rabbit #5 at 28 days were noted. These responses were believed to be related to inadvertent infection associated with surgical implantation and not due to reaction to the implanted mesh materials.

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Table 1

TISSUE RESPONSE TO PROLENE* MESH
3 DAYS POST IMPLANTATION SUBCUTANEOUSLY IN RABBITS

al	Rabbit No.	Sex	Site	Overall Response	Comments on Response
Mesh 0-3	1	M	Left	Slight	Two sections examined. Slight hemorrhage and edema peripheral to implant. Minimal heterophil infiltration was noted around 10-20% of fibers. Early granulation tissue around implant fibers.
	2	M	Right	Minimal	Two sections examined - minimal granulation tissue formation; delicate connective tissue and vascular proliferation around implanted fibers the only reaction noted.
	3	M	Left	Minimal	Details same as 2R.
	7	F	Left	Slight	Two sections examined. Implant was folded in site. Details of response similar to #1 left.
	8	F	Right	Slight	Two sections examined. Implant folded in site. Slight sero-fibrinous exudate, slight hyperemia and extravasation of erythrocytes noted around mesh fibers. Occasional focus of heterophils around fibers was noted.
	9	F	Left	Minimal	Two sections examined. Minimal inflammatory response noted. A few macrophages around some implant fibers were seen. Early fibroblast proliferation in spaces was seen.

06015

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Table 2

TISSUE RESPONSE TO MARLEX MESH
3 DAYS POST IMPLANTATION SUBCUTANEOUSLY IN RABBITS

al	Rabbit No.	Sex	Site	Overall Response	Comments on Response
esh D-2	1	M	Right	Moderate	Two sections examined. Moderate diffuse heterophil infiltration in area of implant; also slight congestion and hemorrhage along with minimal edema. Pronounced macrophage infiltration adjacent to about half of filaments in sections.
	2	M	Left	Minimal	Two sections examined. Separation of adjacent tissues made assessment difficult. Minimal hyperemia and edema around filaments. A few macrophages were seen around about 10 percent of filaments. Areolar-like connective tissue noted between filaments.
	3	M	Right	Minimal	Two sections examined. Response same as for #2 left.
	7	F	Right	Slight	Two sections examined. Implant was folded. Slight edema, slight hyperemia and minimal hemorrhage were seen around mesh fibers. Minimal heterophils and macrophages in implant sites were noted.
	8	F	Left	Slight	Two sections examined. Response same as for #7 right.
	9	F	Right	Minimal	Two sections examined. Response same as for #2 left.

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Table 3

TISSUE RESPONSE TO PROLENE* MESH
28 DAYS POST IMPLANTATION SUBCUTANEOUSLY IN RABBITS

Rabbit No.	Sex	Site	Overall Response	Comments on Response
ish 3	4	M Right	Slight	Moderate fibroblastic cell proliferation along with slight vascular proliferation around filaments and in spaces between filaments. Occasional giant cell and a few macrophages adjacent to some filaments; two sections examined.
	5	M Left	Moderate	In one section a granulomatous reaction surrounding a pyogenic focus of heterophils adjacent to mesh filaments was seen. In the second section a moderate granulation tissue reaction similar to that noted for #4R without suppurative response was seen.
	6	M Right	Slight	Two sections examined. Response as in #4 right.
	10	F Right	Slight	Two sections examined. Response primarily fibroblastic proliferation around mesh fibers and filling in spaces. Minimal vascular proliferation. Occasional giant cells, macrophages, and eosinophils seen around filaments. Implant was partially folded over.
	11	F Left	Slight	Two sections examined. Moderately dense fibrous tissue around filaments and in mesh spaces. Slight foreign body response with scattered giant cells and macrophages around some filaments.
	12	F Right	Minimal	Two sections examined. Implant was folded. Primary characteristics were moderate proliferation of blood vessels and fibroblasts around fibers and in mesh spaces. Scattered giant cells, macrophages and lymphocytes noted around fibers.

06017

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-7-

Table 4

TISSUE RESPONSE MARLEX MESH
28 DAYS POST IMPLANTATION SUBCUTANEOUSLY IN RABBITS

1	Rabbit No.	Sex	Site	Overall	Comments on Response
				Response	
1-2	4	M	Left	Slight	Two sections examined. Implant folded. Primary response was proliferation of loose fibrous tissue around filaments and in mesh spaces. Slight foreign body giant cell reaction noted.
	5	M	Right	Slight	Two sections examined. Primary response was moderately dense fibrous tissue proliferation around mesh filament and filling mesh spaces. One to several foreign body giant cells seen adjacent to about 50 percent of filaments.
	6	M	Left	Slight	Two sections examined. Details of response same as #5 right.
	10	F	Left	Minimal	Implant in one section only. Slight connective tissue proliferation among mesh filaments. Minimal foreign body giant cell formation noted.
	11	F	Right	Slight	Implant in one section only. Details of response same as #5 right.
	12	F	Left	Slight	Two sections examined. Skin was absent; had been reflected from site for gross photograph at necropsy. Slight connective tissue proliferation around filaments. Slight foreign body giant cell formation around 50-60 percent of filaments.

06018

ETH.MESH.06398841

Tissue Reaction and Tensile Strength of PROLENE Polypropylene Suture
In-Vivo

(Ethicon Limited Report No. 38/82, 27.9.82)

06019

Summary

Blue dyed PROLENE sutures, gauge sizes metric 1.0, 2.0 and 4.0 were implanted into the lumbar muscle of rats for periods up to 18 months. Three rats were used for histological evaluation and three for breaking strength assessment at each survival time.

Very few rats survived beyond one year due to a pathological problem associated with the strain of rat used.

Tissue Reaction Assessment

Tissue reactions were described qualitatively and assessed quantitatively using a manually operated picture analyser. Tissue reaction areas from 1 to 120 days were between 0.11 and 0.42 mm² indicating an extremely low grade reaction which was unchanged at the longest period tested - 18 months.

Tensile Strength Assessment

Straight pull tests using an Instron tester were carried out on the explanted samples. PROLENE was shown to be very resistant to loss of tensile strength at all periods tested.

Study of Tissue Reaction to Colourless and Pigmented Polypropylene
Sutures in the Ocular Tissues of the Rabbit

(Ethicon Inc Final Report, 14.10.65)

Summary and Conclusions

The reaction to size 5/0 colourless and pigmented sutures in tissue of rabbit eye was investigated in two series of experiments. In one group of 29 albino rabbits straight segments of sutures were placed in the palpebral conjunctiva. Four rabbits from this group were killed at 3, 5, 7, 10, 30 and 60 days after implantation.

Histological evaluations were made of 11 sites implanted with colourless sutures and 17 sites implanted with pigmented sutures. In the second experiment sutures were evaluated in the rectus dorsal muscle and palpebral conjunctiva of 20 rabbits. Animals were killed after periods of 3, 7, 30 and 60 days, histological evaluations were made of 32 sites implanted with colourless sutures and 32 sites implanted with pigmented sutures.

Suture implants caused no appreciable damage to host tissues, the most characteristic reaction being a slight chronic inflammation. The implants retained their original characteristics and appeared to be completely inert.

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VI.2. CARCINOGENICITY STUDIES

- Report of study by ETHICON Limited, 10/14/65

06021

Two Year Study of Tissue Reaction to Colourless and Pigmented Monofilament Polypropylene Sutures in the Dog

(Ethicon Inc Final Report, 14.10.65)

Summary and Conclusions

The biological behaviour of colourless and copper phthalocyanine blue pigmented polypropylene sutures was determined in four dogs in a two year study. Sutures, size 5/0 and 2/0, were implanted in the latissimus dorsi muscle as straight segments, continuous looping stitches, and as interrupted stitches. One dog was killed for histological evaluation of implant site after three months; the remaining three dogs after two years.

On gross examination the severed ends of the implanted segments appeared intact; no untoward reactions were noted.

Microscopically the sutures appeared as translucent, colourless or blue circles or ovals with regular outlines; neither phagocytosis of the implants nor dissolution were observed. Small fragments of polypropylene were seen in the vicinity of a few implants, both colourless and pigmented. These probably shredded off when knots were tied.

The reaction to the suture in most of the sites was slight and consisted of fibrous capsules infiltrated with varying numbers of macrophages. A somewhat larger number of macrophages and lymphocytes was seen in four implants, two colourless and two pigmented sutures. Since part of each of these implants was sutured into both muscle and fascia the increased reaction was probably caused by adhering tissues pulling on the sutures during movements of the animals. The type of reaction to colourless and pigmented sutures was similar as was the reaction after three months and after two years.

No neoplastic changes were observed.

Colourless and pigmented monofilament polypropylene sutures were well tolerated by dog tissue, caused a slight foreign body reaction, were not carcinogenic and were not absorbed within 24 months.

06022

Two Year Study of Tissue Reaction to Colourless and Pigmented Monofilament Polypropylene Sutures in the Rat

(Ethicon Inc Final Report, 14.10.65)

Summary and Conclusions

Colourless and phthalocyanine blue pigmented polypropylene sutures, sizes 2/0 and 5/0 were implanted into muscles and subcutis of 199 Sprague-Dawley rats. Rats were killed at intervals over a period of 24 months; implants and tissues were evaluated grossly and microscopically.

The reaction to colourless or pigmented suture in 45 rats maintained on test for 18 months or more was minimal, characteristic of a relatively non-irritating foreign body. The implants were surrounded by thin fibrous capsules whose interphase was infiltrated with few macrophages and fibroblasts. Several capsules hyalinised; giant cells were rarely seen. Reaction to both types of sutures after two years did not differ from that observed at one year. Microscopically, neoplastic changes in proximity of any suture were not observed, and all implants appeared intact grossly and microscopically.

On the basis of the experiment it was concluded that both colourless and pigmented polypropylene sutures were well tolerated by rat tissues, caused minimal foreign body reaction, were not carcinogenic, and were not absorbed during the 24 months test period.

VII. B I B L I O G R A P H Y

ETHNOR SA - PROLENE® Mesh Technical File - BP - July 1995 Section 7 Page 2

VII.1. ABDOMINAL WALL

(SELECTION)

1. Indications for selected operating methods in the treatment of post-operative ruptures of the antero-lateral abdominal wall.

R. STOPPA, X. HENRY, J.P. CANARELLI, S. LARGUECHE, P. VERHARGHE, D. ABET AND R. RATSILALAKA

Memoires de L'Academie de Chirurgie 105(4), 276-286, 1979

2. Management of acute full-thickness losses of the abdominal wall

H. HARLAN STONE, TIMOTHY C. FABIAN, MARGARET L. TURKLESON, MAURICE J. JURKIEWICK.

Annals of Surgery 3(5): 612-8. 1981

3. Comparison of prosthetic material for abdominal wall, reconstruction in the presence of contamination and infection.

GREGORY L. BROWN, DAVID RICHARDSON, MARK A. MALANGONI, GORDON R. TOBIN, DOUGLAS ACKERMAN, HIRAM C. POLK

Annals of Surgery 201(6): 705-11. 1985

4. Polypropylene mesh closure of infected abdominal wounds

JON W. JONES, GREGORY J. JURKOVICH

The American Surgeon 55: 73-6. 1989

5. Synthetic mesh in the repair of incisional hernia

GC. GOONETILLEKE

Ceylon Medical Journal 37(3): 87-9. 1992

6. Incisional hernia

THOMAS A. SANTORA, JOEL J. ROSLYN

Surgical Clinics of North America 73(3): 557-80. 1993

07003

Indications for selected operating methods
in the treatment of post-operative eventrations
of the antero-lateral abdominal wall.
Proposals based on a series of 326 cases
by

R. Stoppa, X. Henry, J.P. Canarelli, S. Largueche, P. Verhaeghe, D. Abet and
R. Ratsivalaka (*)

(*) Research from the Surgical Clinic of the UHC of Amiens.

Summary

The authors describe recent advances in operative procedures, which are related to the anatomy of the lesion, the physiopathological effects of severe eventrations, and the changes occurring in the lesion. This information can be used to improve analysis of individual prognosis, to improve patient preparation, to better evaluate the risk of possible failure of operative treatment, and for considering that wide prostheses with peritoneal reinforcement are the most satisfactory ones.

A critical study is made of the technical solutions available: raphes, true plastic procedures, autotransplants, and prostheses. The authors consider that among the prostheses, their choice would be one with peritoneal reinforcement with dacron tulle inserted without fixation (biological glue can be of interest here) into one deep divisible site of the parietal layers. The risk of sepsis can be avoided, or it must be treated, while conserving the prosthesis. Three methods are suggested as being valid: raphes for eventrations without "loss of substance"--"buried skin flaps in situ" for the most hazardous conjectures--inserted prostheses for the routine treatment of large eventrations.

A chart summarizing these opinions is presented, showing operative indications as a function of the site and extent of the eventration and its complications (sepsis, strangulation, relapse), and a multicenter study is suggested in order to make further advances in this direction.

The numerous failures, although difficult to quantify, that burden the surgical treatment of major post-operative eventrations should cause surgeons to have a spirit of inquiry with respect to this "iatrogenic" pathology which concerns them very specifically. At present, the recent factors capable of causing a reasoned development of tactics and techniques are the possibility of better analysing the circumstances and their physiopathological consequences, of preparing the patients better, and of better assessing the risks of failure in the traditional procedures, and finally of using selected procedures among which the large prostheses for peritoneal reinforcement occupy an important place.

We shall attempt here to give a critical tactical statement capable of enhancing the value of certain techniques at the expense of the traditional confidence accorded to others. Our experience has led us to adopt a chart of the indications of a reduced number of techniques judged to be reliable. It is this planning and these reflections that we are submitting for your appraisal.

I. The factors that should inspire the surgical tactics

I.1. The anatomy of the lesion

I.1.1. In practice, the eventration lesion is defined by its location, of course, but above all by the evaluation of a certain number of anatomical facts which when taken into account define the concept of "loss of parietal substance" (LPS) which implicates the difficulties of repair using the structures found at the site. Major eventrations, with a neck of more than 10 cm, are all LPSs for which repair is in principle very uncertain. To us, a diameter of less than 5 cm corresponds to a minor eventration without LPS. Between 5 and 10 cm in diameter, some eventrations with a poor wall should be considered like the LPSs. In reality, it is difficult to assess clinically the exact dimensions of the neck of an eventration, in particular when staggered eventrations are involved or when a septic event intervening in the etiology has caused a secondary fibrous degeneration of the edges.

I.1.2. For J. Rives (10), the facts to be taken into consideration are, above all, in the case of median eventration: the recoil of the insertions of the large muscles and their atrophy, as shown by the histological and biological examinations (cf. also J.P. Arnaud (4)); the sagitalization of the rectus muscles and the enucleation of the abdominal contents, under the action of the contractions of the abdominal support musculature, a factor in the loss of the "domiciliary right."

Another important element in the anatomical picture is the reducibility or non-reducibility of the content, about which we shall speak later.

It is also necessary to emphasize the complexity of the lesions encountered in multirecurring eventrations which end up by being considered as beyond therapeutic resources, although the risk of strangulation remains. Is this not a reason to assess with care the risks of failure of the traditional repair procedures so as to choose the most reliable techniques to start with? Finally, we want to emphasize the importance of the peritoneal infundibulum, a central element in the lesion which the repair should suppress as a "radical" zone. It must be accepted that there is eventration each time the plane of the fascia transversalis is crossed by the visceral sac. We deduce from this that the only "radical" therapeutic method is that which renders the visceral sac ideally inextensible, whatever the condition of the wall. In our current conception, this ideal method is the enveloping of the peritoneal sac by a flexible and sturdy large-size prosthesis which prevents recurrence (16).

I.1.3. All in all, the typical eventration, the problem eventration, is a major sub-umbilical median eventration because of its disastrous physio-pathological consequences and the practical difficulties of repairing it, resulting essentially from the loss of the "right to the city" of the "2nd abdomen" (Goni-Moreno) and the disproportion between the inadequacy of the remaining parietal structures and the dimensions of the breach to be repaired. Eventrations of the thoraco-abdominal, ilio-abdominal or lumbo-abdominal borders offer repair difficulties associated with the existence of a skimpy edge on which the attempts at reinsertion of the support musculature are tricky.

I.1.4. In our own series of 326 post-operative eventrations we have compiled 253 major eventrations (77%), 38 moderate eventrations (11.6%) and 35 minor eventrations (10.7%); with a total of 62 recurrent eventrations (19%).

I.2. Physico-pathological repercussions of major eventrations

The physiology of the abdominal wall is strongly associated with the mechanics of ventilation; this physiological interdependence between abdominal wall, diaphragm and thoracic cage has become as familiar to the surgeon as to the anesthesiologist-resuscitator. We give less thought to how much the abdominal wall participates, with the diaphragmatic pump, in the return circulation and, in opposition to the retrorachidic musculature, to the statokinetics of the trunk.

I.2.1. Eventration: ventilation disorder

The original concept of J. Rives on a respiratory eventration disorder (9) has the merit of inspiring our surgical indications and of giving a physiological purpose to our techniques. The LPS represented by the eventration brings about poor functioning of the diaphragm; at the level of the LPS itself, the wall, reduced to teguments, behaves like a shutter animated by paradoxical movements at the times of respiration. The respiratory eventration disorder is varied slightly by anatomical and clinical factors. The irreducibility of the content permits a "normal" functioning of the diaphragm by maintaining an intra-abdominal pressure before the operation, but implies a risk of ventilatory distress after surgical reduction of the content. Goni-Moreno has asserted since 1947 that the reduction of the content corresponds to the existence of an abdominal shutter, a factor for latent ventilatory insufficiency, liable to sudden decompensation due to low intra-abdominal pressure.

I.2.2. Eventration: circulatory disorder

This additional "tare" is shown in two ways, *systemic inferior vena cava stasis* due to inefficiency of the diaphragmatic pump and *splanchnic venous stasis* due to low intra-abdominal pressure. The consequences of this stasis are different in the pre- and post-operative phases. The post-operative thrombo-embolic risk is greater for major eventrations because of the associated respiratory disorder.

I.2.3. Eventration: vascular disorder

I.2.3.1. The parietal lesions of major median eventrations (muscular atrophy, sagittalization of the rectus muscles and recoil of the insertions of the lateral support musculature) can cause a statokinetic defect of the trunk, with lumbar lordosis, the significance of which depends on the inefficacy or the destruction of the anterior bracing by the "martingale" of the rectus muscles.

I.2.3.2. Inspired by various researches on the electromyelographic study of the muscles of the antero-lateral wall of the abdomen, with D. Abet (1) we tested the large rectus, large oblique and small oblique muscles with respect to 11 parietal areas in 100 patients with major eventrations. The results obtained can be classified quantitatively into 5 groups, according to whether the area is inactive (I), slightly active (II), moderately active (III), active (IV) or very active (V). Qualitatively, 5 areas seem to be the most interesting to explore, 1 and 10 corresponding to the large rectus, 4 and 9 to the large oblique and 11 to the small oblique muscles.

Taking into account the individual variability of the responses, and averaging the responses in the five main areas, we have available an overall criterion for the electromyelographic activity of the muscles of the abdominal support musculature. All together, the results, divided up into the five quantitative groups in the 100 cases tested, are as follows: 12 cases were classed in Group I, 20 cases in Group II, 48 cases in Group III, 12 cases in Group IV and 8 cases in Group V. There is no rigorous parallelism between the size of the eventration and the poor quality of the electromyelographic test but 80/100 major eventrations are found in Groups I, II or III. The future will tell if electromyelography of the muscular wall of the abdomen constitutes a practical criterion that it is indispensable to explore. We have personally derived from it the indication for a much more rigorous preparation of patients with major eventrations and a poor electromyelographic criterion.

I.2.3.3. The trophic disease of the eventrated wall does not only affect the muscles; the surgeon knows these atrophies well that reach all the planes, including the skin. Undoubtedly a recidivism factor is involved here after suturing or plastic surgery utilizing structures found at the site.

I.3. Evolutivity of the existing eventration

I.3.1. The notion of speed of growth of the eventration

This speed results from opposing factors, those that govern the expansion of the existing eventration and those that retard it. The most important factors here are obesity, parietal deterioration, the site of the eventration and the causes of high intra-abdominal tension (colopathy, exertion, etc.).

If it is difficult to predict the speed of growth for a given case, it is possible to characterize this speed by considering groupings of cases. For example, for a subject of average corpulence, epigastric eventration has a rate of growth higher than that of sub-umbilical eventration, but it stabilizes in 3 to 6 months whereas sub-umbilical eventrations with a large neck continue to grow regularly and for much longer. A thin subject with a poorly developed muscular wall makes eventrations that have a very slow rate of growth and relatively rapid stabilization, sometimes with a large neck but insignificant sac and bulging. Extreme evolutivities are represented by very tiny eventrations on one hand and by covered eviscerations on the other.

For us, taking the notion of speed of growth into consideration brings different therapeutic indications; we shall return to this.

I.3.2. Evolutive problems

We shall only cite those that, regardless of the operative risk, require a rapid or emergency surgical decision: repeated obstruction represents, besides again bringing into question the sometimes precarious equilibrium, a circumstance that stealthily aggravates the degenerative sclerosis of the parietal structures; strangulation, not always easy to confirm, endangering the vital prognosis and the early and prudent use of the pneumoperitoneum has been of service here in some cases by de-dramatizing a "tense" situation.

I.3.3. Preparation of the patient and the pneumoperitoneum (Goni-Moreno (18))

This involves measures that are capable of influencing the evolutivity of an eventration either because it is at a critical phase of its progress (obstruction, strangulation), or to improve the overall condition of a patient with a major eventration with a view to parietal repair.

We are completely convinced by the many works of Goni-Moreno that the preparatory pneumoperitoneum should be part of the pre-operative conditioning of major eventrations because not only does it improve the circumstances of the lesion, but it often also reduces the harmful consequences of major eventration on the ventilation and the sub-diaphragmatic venous circulation. In our series, we have used preparatory pneumoperitoneum 123 times in the group of 253 major eventrations (48.6%) with a very reduced number of minor incidents: scapular pain, 19 cases; parietal hematoma, 7 cases; parietal emphysema, 4 cases; retroperitoneal emphysema, 3 cases. The selection of the patients was made by the Goni-Moreno criteria (18). The average total amount insufflated was 10.5 l. The average duration of the preparation was 10 days with extremes of 4 days and 28 days.

Other contributions to the pre-operative preparation are a weight loss program and respiratory kinesitherapy; that is, a complex, sometimes long preparation is involved which can only be applied to its fullest extent in slow-growing eventrations.

1.4. Conclusions

I.4.1. A brief recall of the factors governing the technique of the surgical treatment of major eventrations, although combining factors of unequal importance, allows us to lay stress on: the necessity of approaching the problem of the surgical treatment of eventrations in the spirit of clinical research that is indispensable for the advent of the progress that remains to be achieved in the reliability of our parietal restorations; the usefulness of analysing the components of the lesion and the long-term repercussions so as on one hand to define the anatomical and physio-pathological objectives of the projected surgical operation, and on the other to assure the best pre-operative conditioning of the patients by appropriate preparation; and finally, to arrive at a universal classification of cases which would permit better evaluation of the observations and probably a better-founded choice of techniques depending on the precise evaluation of the hazards arising from the conditions.

I.4.2. In practice, it is now possible to put forward the following proposals:

- a) Major eventrations are not only "holes to be plugged" but also a local and regional disorder affecting the mechanics of ventilation, sub-diaphragmatic venous circulation and spinal statokinetics.
- b) Their repair must call on differential indication procedures: suturing and comparable procedures are only rarely possible or even desirable because of the consequences of the LPS; autoplasties using vicinal parietal structures are open to criticism because they add damage.
- c) "Edge-to-edge" "patching together" with transplants or prostheses brings a partial solution of moderate solidity to the local problem and to the long-term physiopathological repercussions by reestablishing a relatively normal intra-abdominal pressure.

d) Large prostheses to reinforce the peritoneal sac are the most satisfactory whatever the dimensions of the LPS and the parietal degradation, at the same time as they normalize the respiratory, circulatory and statokinetic conditions.

II. Critical study of technical solutions

II.1. Suturing and derived procedures

II.1.1. We hardly ever use these well-known procedures using structures found at the site which are sutured without tension with non-absorbable thread. They include extra-peritoneal procedures (Quenu, d'Allaines and Contiades) and intra-peritoneal procedures, observing Condamin's principle (mattress suture of W. Mayo and Judd; procedure of Welti-Eudel).

It is possible to find some interest here in the "pulley" stitch which cuts less. Repair at several levels has less resistance to infection and traction "Support stitches" at a distance do not appear to bring additional security.

II.1.2. The standard indications for sutures and their derivatives are small and moderate eventrations such as partial eventrations after septic elimination of a wall suture thread and lateral eventrations in a drainage path. Overall, eventrations are involved that do not have true loss of substance from the abdominal wall and have a slow rate of growth. However, these simple procedures cannot be considered to be satisfactory for major eventrations. Undoubtedly, the current suture threads are of good quality, but the tissues brought together are cut if they are subjected to tractions that are too strong. Above all, as J. Rives (11) says, these procedures misjudge the physiopathology of major eventrations; they consist of reclosing the disunited wall like a first laparotomy is reclosed without taking into account the obvious setback and the lesions that appeared with the eventration, nor their physiopathological consequences.

It must also be said that mistakes and abuses have been committed in the name of exclusive re-suturing, such as large "mobilizing" dissections, the generous resection of the epiploon (rear wall of the oriento-parietal fissure), and above all the dangerously debilitating "discharge" incisions.

II.1.3. On the other hand, a little piece of dacron gauze glued over the peritoneal sac is an easily used means of reinforcement, capable of compensating and increasing the value of a re-suturing. We have used this without fail in operations for small eventrations for the last two years.

II.1.4. In the series considered in this work, we used suturing or similar procedures 43 times to treat: 28 small lateral eventrations, with 5 backup patches; 1 single recurrence out of 21 patients operated on and seen again after 6 months or more; 5 small median eventrations with two glued backup patches; no recurrence after 6 months or more; 10 moderate lateral eventrations, with 4 glued backup patches; 1 partial recurrence after 1 year.

II.2. True plastic surgery in situ

II.2.1. We refer here only to the procedures using parietal disinsertions, such as those of Sheerwood and Perelman (mobilizing the chondro-costal border), Daniel's myoplasties splitting the large rectus of the opposite side and Lanson's aponeurotic flaps. These debilitating techniques do not seem advisable to us, although we have no personal experience with them; they can perhaps be attempted in exceptional cases ("peripheral" eventrations).

II.2.2. The criticisms that are applicable to all autoplasties *in situ*, whether they are muscular or aponeurotic, are the following: the duration of the surgical procedure is often too long considering the hazards encountered; the use of structures deteriorated by the eventration, sometimes weakened still more by dissections or "mobilizations," is unsatisfactory and too high a tension resulting from the use of local structures risks the reproduction of the conditions that are at the origin of the eventration.

It thus seems that these procedures should only be considered under exceptional circumstances. Can they be "improved in value" by combining them with a piece of glued preperitoneal dacron gauze? We have no experience with this.

II.3. Autografts (autotransplantations)

II.3.1. We have no experience with aponeurotic (fascia lata) autografts in patches or strips. In the past we have employed the standard procedures using the skin rarely, and the skin lacing proposed by J. Gosset, then by Suire, Laflitte and Pavy, Juzbasic, Theodoreesco, etc., not at all. Occasionally we have used a total autogenous skin transplant (Rehen, Mair, Green, then Pautet, Roux and Laurthe-Tolra, Judet, Morel-Fatio, Gautier-Benoit) (16) or a homogeneous one preserved with "Cialit." It must be remembered that total skin is an easily accessible source of fibrous tissue developed at the expense of the dermis, which can be buried with impunity, provided it is sutured like a "drumskin". Removal of the epidermis is then not useful. The reversal of the transplant seems preferable to facilitate phagocytosis of the epidermal debris in the peritoneal cavity as well as the revascularization of the transplanted dermis. It is useless and probably harmful to realize a complementary layer between the cutaneous transplant and the tegument, because the development of "epidermal cysts" is then a risk, a result of the wrinkling of the graft. The criticisms applicable to this technique are its length and the necessity of a large, sometimes very distant, removal from the abdominal field.

II.3.2. We would like to recall a procedure of our own, published in this journal with our professor J. Seror (12, 13), which we called the cutaneous flap "buried in situ" procedure. This combines the advantages of repairs using structures found at the site with those of plastic surgery, that is, simplicity and efficacy. A simple procedure, it is applicable to patients worried about recovery, but weary. As an extra-peritoneal procedure, it is better to reject it for eventrations with sub-occlusive problems; as a procedure assuring moderate security, the patient must be warned that he will sometimes be required to remain strapped up in a light corset.

II.3.3. In the series considered here, there are no skin patches. We had in the past used the "cutaneous flap buried in situ" procedure about thirty times with consistent results. A.A. Arianoff et al. have recently reported before the Belgian Society for Surgery on a series of 71 cases with 4 failures on 58 patients seen long-term (3).

II.3.4. Even if skin patches are a good answer to the physiopathological constraints of eventrations with major loss of substance and in particular in the conditions created by the eventration respiratory disorder, it is certain that the reliability of the repair is moderate because of the defects inherent in the "patching up" that they achieve. We think that skin patches should be strictly reserved for poor overall conditions both from the point of view of the general conditions and the local state, and in particular to eventrations with risk of infection, eventrations on an irradiated wall, in ascitic cirrhosis, or after covered evisceration (the rapid growth of these latter cases does not always permit a long enough reparation, especially for the pneumoperitoneum).

II.4. Prostheses

These have the advantage over grafts of avoiding the removal time and of being available in any dimensions; however it is only recently that they have become "good prostheses," dacron gauze being the best representative at present.

II.4.1. Metal prostheses

Metallic prostheses, in the form of silver wire, tantalum mesh (Burke 1940) and then steel wire (Thomeret 1960), were abandoned after the failures and accidents that are well known.

II.4.2. Plastic prostheses

These comprise a whole series of synthetic materials, the desirable qualities of which are strength, flexibility, permeability, and good tolerance (2, 7, 8), especially in septic environments, and the adherence to nearby tissues. It seems to us above all that the "gauze" structure is among the most interesting both to assure its light weight and good behavior in case of septic problems and also the rapid autofixation to the walls of the implantation fissure in the parietal layers. The animal experiments that we performed with J. Petit (7, 8) and our clinical experience (about 1000 parietal prostheses) are in agreement and have led us to be loyal to dacron gauze, which was proposed in France by J. Rives (11). We have never used the relatively pliable but impermeable patches of Rhodergon velvet (J. Gosset, Ph. Detrie (5)), or the non-pliable and non-permeable patches of siliconized material (Silastic). It may be recalled that prostheses had initially been used as superficial reinforcements of the suturing of the sheath of the rectus muscles, then after 1944 for the pre-peritoneal patching up of the loss of parietal substance, either at the deep face of the muscles, in front of the sutured peritoneal plane (Usher, Stock, Acquaviva), or in front of the posterior layer of the sheath of the rectus muscles (J. Rives (10, 11)), or on the superficial face of the rectus muscles (Chester Barclay) with more risks of infection. Around 1955, Usher, Bourgeon advocated their use intraperitoneally in direct contact with the viscera.

II.4.3. This type of solution theoretically resolves the two main therapeutic problems (9):

- The mechanical problem: to compensate for the insufficient parietal structures;
- The physio-pathological problem: to restore a moderate abdominal pressure in order to treat the ventilatory disorder by reestablishing the conditions of normal diaphragmatic functioning.

However, the prosthesis introduces a septic risk which is accompanied by constraints which we will discuss again. On the other hand, "edge-to-edge" patching up subjects the sutures to tensions that can be high and the source of failure.

II.4.4. Personally, we also propose a much more reliable method, adaptable to all LPSSs: the large reinforcement prosthesis for the peritoneal sac which renders the latter non-extensible and prevents recurrence; we have used this for 8 years.

These are the principles of this method:

- a) We chose the Dacron gauze prosthesis for the reasons previously discussed. Its good tolerance permits the use of very large-sized prostheses (30 cm x 30 cm) all the more so since the type of insertion desired is deep.
- b) The choice of the implantation site of the parietal prosthesis is made between four "good," "natural," deep sites in the "laminations" of the abdominal wall: the inferior retro-parietal pre-peritoneal cleavable space (Retzius and Bogros), utilizable for median sub-umbilical eventrations; the sub-umbilical retro-parietal pre-peritoneal space, a little cramped, for median sub-umbilical eventrations; the sub-umbilical retromuscular space, in front of the posterior layer of the sheath, which can be used in median and para-median umbilical and sub-umbilical eventrations; finally, the intra-peritoneal "omento-parietal fissure," which can be used in umbilical and sub-umbilical median eventrations (15).

In our opinion, there are two sites of choice, the plane of the retro-parietal and inferior pre-peritoneal cleavage (used 155 times in our series) and the anterior cleavage plane of the posterior layer of the sheath of the rectus muscles (used 31 times in the series under consideration). Two others are used less frequently, the omento-parietal fissure and the sub-umbilical pre-peritoneal retro-parietal space (used 18 and 16 times, respectively). However, it is very often indispensable to carry out "mixed" implantations (6), by making 2 or more "natural" cleavage fissures communicate by dissecting so as to obtain a very wide peritoneal reinforcement (103 times in our series).

It is thought that the facility of cleavage of these sub-parietal spaces is reduced by successive re-operations. To us, this is one more reason to assess with appropriate seriousness the risk of failure of a traditional cure and to choose from the outset the procedure which best opposes recidivism.

c) The large sizes of the prostheses used contrasts them with "patches" (for parietal "patching") and permits their insertion without direct fixation to the edges of the loss of wall substance; they "hold" by face to face adherence in the parietal cleavage fissure, at first like a "tire patch" between inner tube and tire, secondarily by penetration of the granular tissue then inclusion in the scar fibrosis. It is possible to improve the immediate and early secondary stability of the prosthesis either by reconstituting if possible a more or less resistant superficial plane or by extending beneath it a small number of traction sutures transfixing the whole of the wall peripherally and fastened on "bolsters," or, finally, by using a biological cement sparingly (cf. below).

d) The advantages of insertion without fixation of the prosthesis into the parietal layers relative to "edge-to-edge" patching seem to us to be the reinforcement of the only plane that counts in the most radical concern possible, that for the peritoneal sac, and the non-fixation of the prosthesis which avoids failures due to the points of parietal necrosis due to pulling the fixation threads tight in the standard patching up.

e) The use of a biological cement is an initiative that we have practiced for a little more than two years. The animal experiments that we carried out with D. Abet (1), confirmed by our clinical practice (32 cases), caused us to choose the N-butyl-cyano-acrylate monomer used by neurosurgeons for many years. We use it by pointwise applications to replace the fixation stitches; the "glued" patch mechanically resists tangential traction just as well as when it is fixed by non-transfixing suture stitches. In certain cases it is possible not only to avoid any direct fixation (source of tightening necrosis), but even any indirect temporary fixation using threads fastened on bolsters (relatively delicate to maintain and causing exposure to infection from the skin).

II.4.5. Infectious setbacks associated with the use of prostheses must be discussed. We observe these in about 3% of cases out of several hundreds of operations, that is a rate comparable to that of "sepsis" after hernia treatment without prosthesis. These unpleasant setbacks represent a hazard similar to that of all surgery using a foreign material (orthopedics, cardiovascular surgery, etc.).

We think, with J. Rives (10), that this number can be reduced by taking technical precautions that are very accessible to the general surgeon: suitable operating room ("prosthesis room" or operation programmed "first" after careful disinfection of the room, laminar air flow?), "draping" the operating field, "no-touch technique," local per-operative antiseptic, close

post-operative monitoring. It must be said that the treatment of a septic setback does not imply the removal of the prosthesis even in case of severe infection. The infection must only be rigorously treated by drainage or irrigation-drainage of the suppurated collections, excision of fistular paths, in sum, by meticulous surgery adapted to the infection involved. Under these conditions, septic setbacks almost always heal by localized action preserving the dacron gauze prosthesis. Unfortunately, it is not the same for the "impermeable" prostheses made of Silastic or Rhodergon. It is certainly difficult to completely suppress setbacks associated with the use of prostheses, and the surgeon is confronted by the choice to be made between the septic risk and the risk of recidivism in some cases.

II.4.6. Finally, the indication for repair in the elderly must be weighed because these are long operations, especially when they have to be combined with another surgical procedure, for example at the same time resecting an excess cutaneous fatty apron, usefully, in a large obese woman prepared by a weight-loss treatment (14, 15).

II.4.7. In the series of 326 eventrations considered here, in 287 cases we used a *large dacron gauze prosthesis reinforcing the peritoneal sac*, under the following circumstances: 253 major eventrations (221 median and 19 lateral) and also the 4 repeats that we observed in this group; 28 moderate eventrations (8 lateral and 20 median) as well as one repeat observed in the group operated on by suturing; finally, the repeat median minor eventration mentioned in the group operated on by suturing. We emphasize that 62 recurrent eventrations were all treated with a prosthesis. Here very briefly are the principal results of the 287 large prostheses: 2 early deceases in aged patients due to cardiac insufficiency (a risk that is probably poorly appraised) and pulmonary embolism (verified on autopsy); 6 supurations, of which only 1 required ablation of the patch in the 3rd month. Of 239 patients seen again, we found after 6 months: 7 recurrences of which 2 were on walls that had already supurated; with the other 5, in whom the walls had not yet supurated, partial recurrences were involved that appeared suddenly after traumatism or great effort in large obese patients, twice after repair of low lateral major eventration.

II.5. At the end of the critical account of the operative techniques for dealing with eventrations, we ourselves shall stay with three valuable and ordinary methods:

- suturing and similar procedures (possibly protected by a glued dacron gauze patch), simple techniques that can be used for minor eventrations without loss of parietal substance, with no respiratory disorder;
- skin patches, for which it must be admitted that their resistance is good in septic or dystrophic environments, that they can be appropriate for large losses of substance, but that they give mediocre solidity and finally that when the terrain is deteriorating, it would be better to have recourse to our own "*cutaneous flap buried in situ*" procedure;
- *dacron gauze prostheses* inserted (without direct fixation to the edges - not as patches) into a fissure of the parietal cleavage (one of the deep sites defined above) so as to obtain a wide reinforcement of the peritoneal sac; this method is very reliable, but costly in operating time and blemished by the septic risk associated with the inclusion of prostheses. The use of biological cement seems to us to simplify the immediate fixation of the prosthesis and to promise consistent results.

We will mention only for the sake of completeness the useful contributions represented by post-operative corseting, kinesitherapy and cautious getting out of bed post-operatively.

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III. Selective indications

III.1. These come from taking into account the etiological factors and the factor governing the risk of recidivism. We recall the main elements to be taken into consideration:

- site: lateral eventrations [are] less evolutive than median ones, especially the sub-umbilical median one (problem eventration); peripheral eventrations offer particular difficulties;
- dimensions of the true loss of substance, contrasting small eventrations (without loss of substance) and major eventrations (loss of substance of more than 10 cm in diameter) which make suturing alone hazardous;
- state of the muscular wall: to be explored clinically and perhaps by electromyelography; "good" walls have no atrophy and "bad" ones have muscular atrophy;
- ventilatory after-effects, to be evaluated without fail and to be corrected in very large eventrations by preparation of the patient;
- the rate of growth, resulting from the preceding elements, defining the evolutivity of the parietal lesions, a basic notion that is not always easy to assess individually;
- the possibility of a rigorous preparation adapted to the individual state of the patient, which is also valid as a prognostic test;
- everything that governs the septic risk and which can preclude the use of prostheses;
- finally, the terrain, with the following as the main aggravating elements: age, obesity, high intra-abdominal pressure factors, deteriorating defenses.

III.2. The anatomical and clinical polymorphism of eventrations requires being flexible and agreeing that no single technique permits the resolution of all the problems posed by the repair of major eventrations. However, it is also necessary to be "pessimistic" in the assessment of the risks of recidivism; in other words, even if many eventrations seem "restorable," it must not be forgotten that they will be more efficaciously treated with a prosthesis (Ph. Detrie (5)).

III.2.1. Lateral eventrations

a) Small and moderate eventrations, with a good wall, ordinarily have low evolutivity and minor ventilatory aftereffects; the typical case is the scar of an old, drained appendectomy. Here, suturing is legitimate and reliable, with the extra contribution of a retroparietal patch cemented on to the peritoneal sac for security in the more problematic cases.

b) Major eventrations have a muscular wall that is of poor quality and associated with a fairly rapid evolutivity. The exclusion of the content of the sac moderates the respiratory contribution for the lowest ones; the typical case is the eventration of a scar from a lumbar sympathectomy or nephrectomy by the antero-lateral route. Here it would be better to use a large prosthesis supported underneath in front and glued in back on to the peritoneal sac.

III.2.2. Median eventrations

a) Small ones with a good wall, of negligible evolutivity except in large obese patients with moderate or negligible ventilatory aftereffects, are frequent and represented by "defects" limited by "loosening" of a suture stitch on the linea alba or by the umbilical hernia in the adult. Here a repair can be effected by mattress sutures protected with a retroparietal patch cemented on to the peritoneal sac;

b) *Diastasis of the rectus or small tiered and multiple eventrations* are quite often subjected to the Welti-Eudel procedure reinforced by a glued patch, but it must be stated that a large prosthesis is more reliable here in the least favorable circumstances;

c) *Major eventrations*, especially sub-umbilical ones and even more so sub- and superumbilical eventrations after xiphopubic laparotomies for aortic surgery, are very poorly tolerated because of their rapid growth on bad walls and because of the major ventilatory after-effects. They are the typical indication for the very large prosthesis, supported underneath, after careful preparation of the patient. But the cases with risk of sepsis can cause a skin patch to be considered; the "poor risks" in a generally dangerous context can make the use of a cutaneous flap buried in situ obligatory.

III.2.3. Eventrations with peripheral topography

These are the ones that are located in the confines of the thorax and abdomen (after thoraco-phrenolaparotomy, after epicardial implantation of a pacemaker electrode, more rarely after subcostal incision); very near the iliac crest and in the thoraco-lumbar region.

Generally large in size, these LPSs can be repaired by means of large prostheses supported underneath by suture threads fastened on to bolsters transfixing the wall very far from the muscular edges and fixed with spots of cement under the rigid edges (chondrocostal rim or costal insertions of the diaphragm on top, fascia iliaca below). The placement of the L.P.P.R. [large prosthesis for peritoneal reinforcement] by the indirect route is strongly advised here.

III.2.4. Complicated eventrations

a) We will not stress the unfavorable circumstances represented by eventrations on an infected or irradiated wall, or on an ascitic abdomen. Let us say only that here we have had decent results after skin patching. Nonetheless, the realization of septic actions in the abdominal cavity as a rule contraindicates the use of a prosthesis even though we had some very pretty successes with prostheses put in place after intestinal resection or closure of a fistula of the small intestine in the same operating session.

b) Good surgical sense demands doing only what can be done on a wall with strangulated eventration. Resuturing alone is often practiced here, especially if an intestinal resection has been required, but in favorable cases we have been able to use a prosthesis.

c) Finally, recurrent eventrations must make consideration of a prosthesis imperative.

III.2.5. Overall, we willingly acknowledge that the field of indications for the standard means of parietal restoration has shrunk greatly in our practice, while that for very large prostheses for peritoneal reinforcement has expanded greatly. The limits of this last method are in no way determined by the extent of the parietal deterioration, but rather by the septic context on one hand and by general circumstances that are too bad on the other.

IV. Conclusion

What to do when confronted with post-operative eventration? We must recognize that this involves the consequences of the failure of the parietal closure and to analyse the causes of this; assess the evolutive risks of the LPS and its ventilatory and overall after-effects on the patient; evaluate the risks of failure of standard or minor techniques in accordance with a classification that we have tried to outline; prepare the patient rigorously

and appropriately. As far as the technical performance of the parietal repairis concerned: treat with care the "remaining" parietal structures and the large omentum, be restrictive in indications for suturing and autoplasty, have recourse to reasonable indications and without timidity to the large prostheses considered as a means of reinforcement of the peritoneal sac; and personally monitor the operative sequelae for 10 days, especially from the viewpoint of the risk of sepsis.

More practically, the question of "what to do" should be extended to the standard questions: "When?" and "How?". The answers to these questions represent primarily a range of proposals which extend from abstention from surgery (of which we have said little - due to non-indication or contraindication) to emergency surgery on a strangulated eventration. The importance of the rigorous preparation of the patient, and the taking into consideration of the long-term after effects of the disorder, especially the ventilatory ones, must be forcefully emphasized. However, the most important terms of the discussion concern the imperative or relative indications and contraindications for large gauze prostheses, a modern method which best answers the anatomical, clinical and pathophysiological requirements. We have attempted to justify our confidence, matched with constraints with respect to these prostheses, hoping that a multicenter experience will allow new advances in the future.

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Discussion

M. Garbay: I congratulate Stoppa for the quality of his results and above all for the small number of occurrences of sepsis and recidivism.

I think, however, that the sub-peritoneal placement of the patch imposes significant decollements, which can increase the risk of sepsis. I also believe that it is very important to "retighten" the large muscles to correct the physiopathological disorders noted by the author. The abdominal support musculature must find a support point to improve the vertebral statics and the respiratory problems.

Finally, as far as the importance of the pneumoperitoneum advocated by my Professor, Goni-Moreno, is concerned, I would like to recall how much he emphasized the "contracture" of the flanks as evidence of the retraction of the abdominal support musculature, since this tension should disappear when the succession of insufflations has permitted sufficient dilation of the abdominal cavity.

C. Houdard: Mr. Stoppa's communication has highlighted the physiopathology of large eventrations and, in particular, the part played by the disinsertion of the large muscles which take on a sagittal orientation.

Like the speaker, I believe in the essential value of a large prosthesis lining the peritoneal cavity, but it seems important to me to give the muscles their support point. As a consequence of the loss of parietal substance, the aponeurotic suture is not possible under excessive tension. The muscles must thus be given their function by a 2nd Tergal patch, sutured to the edges of the breach. The placement of a 2nd layer of inert material does not seem to have increased the morbidity of the technique.

Ph. Monod-Broca: I congratulate Stoppa on his excellent paper and the results he reports. I am only sorry that he did not formally distinguish between super-umbilical and sub-umbilical eventrations. For the latter, a prosthesis can almost always be avoided in favor of musculo-aponeurotic plastic surgery. Even so, the risk of sepsis is less for the latter technique.

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Management of Acute Full-thickness Losses of the Abdominal Wall

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Over a 20-year interval, 167 patients sustained acute full-thickness abdominal wall loss due to necrotizing infection (124 patients), destructive trauma (32 patients), or en bloc tumor excision (11 patients). Polymicrobial infection or contamination was present in all but five of the patients. Of 13 patients managed by debridement and primary closure under tension, abdominal wall dehiscence occurred in each. Only two patients survived, the 11 deaths being caused by wound sepsis, evisceration, and/or bowel fistula. Debridement and gauze packing of a small defect was used in 15 patients; the single death resulted from recurrence of infectious gangrene. Pedicled flap closure, with or without a fascial prosthesis beneath, led to survival in nine of the 12 patients so-treated; yet flap necrosis from infection was a significant complication in seven patients who survived. The majority of patients (124) were managed by debridements, insertions of a fascial prosthesis (prolene in 101 patients, marlex in 23 patients), and alternate day dressing changes, until the wound could be closed by skin grafts placed directly on granulations over the mesh or the bowel itself after the mesh had been removed. Sepsis and/or intestinal fistulas accounted for 23 of the 27 deaths. Major principles to evolve from this experience were: 1) insertion of a synthetic prosthesis to bridge any sizable defect in abdominal wall rather than closure under tension or via a primarily mobilized flap; 2) use of end bowel stomas rather than exteriorized loops or primary anastomoses in the face of active infection, significant contamination, and/or massive confusion; and 3) delay in final reconstruction until all intestinal vents and fistulas have been closed by prior operation.

ONE OF THE MOST PERPLEXING situations ever to confront the general surgeon is an open abdomen in the absence of adequate somatic substance to effect secure closure of the peritoneal cavity.¹⁻⁶ An obsession with the necessity to obtain fascia to fascia approximation, regardless of the tension, has appeared to be the overriding determinant of what action is taken to gain such an end. If, on the other hand, the surgeon attempts to obviate undue tension on the suture line, his debridement of contused and inflamed tissues becomes all too conservative for the massive nature of associated

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bacterial contamination. In either event, the outcome is uniformly predictable. There is the rapid onset of a necrotizing wound infection, which in turn serves as the initiating focus of a progressive, fulminating, and often lethal, more generalized, sepsis.

A modest experience in the management of patients with acute full-thickness defects of the abdominal wall has led to the identification of certain surgical tenets. Unfortunately, failure, especially if repetitive after a specific method of repair, has been much more instructive than has any success. In addition, correction or control of associated injuries and disease states may, in final analysis, hold the balance between eventual life and death.

The following is a retrospective review of these patients, as cared for on the Surgical Service of Grady Memorial Hospital.

Patient Review

During the 20 year interval from 1960 through 1979, 167 patients had major abdominal wall defects created by external violence, necrotizing soft tissue sepsis, or en bloc excision of primary or secondary neoplasia. The average age of the patients was 44.6 years, with a range of 3 to 84 years. There were 118 males and 49 females, 106 black patients and 61 white patients.

These large somatic defects were the result of radical debridement in 124 patients with necrotizing soft tissue sepsis, destructive abdominal wall trauma in 32 patients, or a sizable full-thickness gap consequent to wide en bloc tumor excision in 11 patients (Table 1). Associated disease states reflected an impairment in host defense function, such as diabetes mellitus and renal disease, or extremes in nutrition (Table 2). Prior laparotomies had been performed either for repair of transperitoneal hollow viscus injuries in 58 patients or

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TABLE 1. Cause for Abdominal Wall Loss

	Number of Patients	Died	Mortality Rate (Per Cent)
Necrotizing infection	124	31	25
Traumatic wound	32	12	38
En Bloc tumor excision	11	2	18
Total cases	167	45	27

for corrections of intra-abdominal alimentary tract inflammatory processes in 46 patients.

Necrotizing Infection

Necrotizing infection of the abdominal wall was caused by a polymicrobial synergism between aerobic gram-negative rods and various anaerobic species in 111 patients (Table 3). Meleney's cellulitis and noma accounted for one symbiotic infection each. Classic gas gangrene occurred in seven patients, while pure aerobic streptococcal erysipelas led to extensive tissue necrosis in the remaining four patients.

The severity of the sepsis was reflected by the fact that 83, or 67%, of the 124 patients had an associated bacteremia (Table 4). Aerobic gram-negative rods, various anaerobes, and Enterococcus were the pathogens almost exclusively isolated from the blood. Clostridial bacteremia was attended by the highest mortality rate of any, i.e., 54%.

Closure of the abdominal defect by approximation of debrided wound edges in two patients fostered a recurrence of sepsis, which then progressed on to fatal septicemia (Table 5). In two other patients, septic death resulted similarly from use of a pedicled abdominal flap. However, when the defect was relatively small, as in eight patients, and could be bridged by a gauze pack, persisting sepsis and eventual death followed in only one so managed. In 112 patients, larger defects not lending themselves to closure by a gauze plug were handled

TABLE 2. Associated Disease States in 124 Patients

Associated Disease	Number of Patients
Diabetes mellitus	61
Cardiovascular disease	43
Renal insufficiency	33
Advanced liver disease	21
Obesity	46
Malnutrition	17
Prior operation for trauma	58
Prior operation for gastrointestinal disease	46
Miscellaneous disease states	81

TABLE 3. Bacteriology of Necrotizing Infections

	Number of Patients	Died	Mortality Rate (Per Cent)
Streptococcal	4	1	25
Gas gangrene	7	4	57
Meleney's syndrome	1	—	—
Noma	1	—	—
Polymicrobial synergy	111	26	23
Total patients	124	31	25

by insertion of a piece of synthetic mesh. Wound sepsis recurred and required at least one additional major debridement in 34 patients, (30%). Death followed in 24 patients (21%) as a result of such persisting sepsis with or without an associated small bowel fistula.

Overall, there were 29 deaths due to progressive wound sepsis, fulminating peritonitis, and/or bowel fistula, thereby producing a mortality rate of 23% on the basis of wound complications alone (Table 5). Two patients died of unrelated causes.

Destructive Trauma

Close-range shotgun blasts were responsible for 21 of the 32 abdominal wall losses caused by trauma (Table 6). An impalement accounted for five abdominal wall losses, while high velocity missiles and guillotine-like injuries, inflicted by railroad boxcar wheels, created three each. The majority of these patients (29 or 91%) presented with a penetrating wound of the abdomen. Other clinical findings included obvious evisceration, hemorrhagic shock in 22 patients, impalement in five patients, and traumatic hemipelvectomy in three patients.

An average of 3.3 associated organ injuries were noted in 31 of the 32 patients (Table 7). Gastrointestinal wounds were present in 30 of these 31 patients, and accounted for many of the postoperative septic complications. However, the greater amount of initial operative effort was directed toward control of the 13 associated major vascular injuries.

TABLE 4. Bacteremia/Septicemia in 83 of 124 Patients

	Number of Patients	Died	Mortality Rate (Per Cent)
Gram-negative rods	69	24	35
Clostridia	13	7	54
Other anaerobes	63	17	27
Enterococcus	32	7	22
Other streptococci	9	2	22
Staphylococcus aureus	5	1	20
Total patients	83	39	35

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TABLE 5. Management of Defects Due to Necrotizing Infection

	Number of Patients	Wound Sepsis/Necrosis	Peritoneal Sepsis	Bowel Fistula	Died of Complications	Died of Other Causes
Primary closure	2	2	2	—	2	—
Gauze pack	8	3	2	1	1	—
Pedicled flap	2	2	2	1	2	—
Mesh prosthesis	112	34	17	7	24	2
Total patients	124	41	23	9	29	2

Primary closure of the abdominal defect, under tension in nine patients was followed by wound sepsis in all nine, peritonitis in four, bowel fistula in three, and death due to one or some combination of these complications in eight patients (89%) (Table 8). Six small wounds were successfully managed without complication by insertion of a gauze pack. Another three patients survived despite local wound necrosis when pedicled flaps were mobilized for closure. When a mesh prosthesis was used to bridge the gap in 11 patients, wound sepsis developed in three and there was one death due to this complication. Exclusive of the three patients who died in the immediate postoperative period as a result of hemorrhagic shock, the nine deaths caused by wound sepsis and/or intestinal fistula gave an overall mortality rate of 28% as a direct consequence of complications arising from wound management.

Fulminating wound sepsis and severe peritonitis were major factors in the disruption of gastrointestinal suture lines. Dehiscence of a small bowel repair or anastomosis occurred in four (15%) of the 27 patients requiring such. By contrast, only two of seven primarily established large bowel suture lines failed. All seven of the gastric and/or duodenal repairs remained intact.

En Bloc Resection

Eleven patients had major abdominal wall defects created by wide en bloc excision. Carcinoma of the colon was the responsible lesion in five patients, abdominal wall sarcomas in four patients, and a teratoma and recurrent nephroblastoma in one patient each.

Both of the patients managed by primary closure of the abdominal wound under excessive tension de-

veloped wound necrosis and infections (Table 9). In one, this progressed to peritonitis, bowel fistulization, septicemia, and death. There were no fatalities as the result of wound complications in the remaining nine patients, although five of the seven treated by primary closure with a pedicled flap had significant wound sepsis and/or necrosis.

Wound Management

Without exception, primary closure of the abdominal wall under tension preceded serious problems with wound necrosis and infection in each of the 13 patients thus treated (Table 10). The mortality rate was 85% on this basis alone. However, for small defects, that is, those with a diameter of less than 8 cm, gauze packing prevented evisceration and gave an acceptably low incidence of major wound complications in 15 patients. Pedicled flaps, on the other hand, did allow the wound to be closed initially without excessive tension, yet significant infection and/or necrosis of the wound occurred in ten of the 12 patients treated in this manner. Insertion of a fascial prosthesis of synthetic mesh was reserved for the larger and more massively contaminated defects as well as for patients with established sepsis that had reached an advanced stage. Still, wound infection recurred or developed in only 37, (30%) of the 124 patients, while a specific wound complication, such as more generalized sepsis or intestinal fistula led to death in 25 (20%) of the patients.

TABLE 7. One Hundred and One Associated Injuries in 32 Patients

Type of Injury	Number of Patients
Gastrointestinal	30
Urinary	14
Major vascular	13
Hepatobilary	11
Spleen	3
Pancreas	2
Skeleton	11
Lung	5
Miscellaneous	12
None	1

TABLE 6. Mode of Injury

	Number of Patients	Died	Mortality Rate (Per Cent)
Shotgun blast	21	9	43
Impalement	5	1	20
High velocity missile	3	1	33
Boxcar wheel	3	1	33
Total cases	32	12	38

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TABLE 8. Management of Defects Due to Trauma

	Number of Patients	Wound Sepsis/Necrosis	Peritoneal Sepsis	Bowel Fistula	Died of Complications	Died of Other Causes
Primary closure	9	9	4	3	8	—
Gauze pack	6	—	—	—	—	—
Pedicled flap	3	3	—	—	—	—
Mesh prosthesis	11	3	2	—	1	—
Operative death	3	—	—	—	—	3
Total patients	32	15	6	3	9	3

Complications of the abdominal wound did play a significant role in determining eventual survival, in that the mortality rate was 60% if wound sepsis and/or necrosis, peritonitis, or bowel fistula developed, but the mortality rate in the absence of such was only 3%, i.e., three deaths of 99 patients (Table 11). Peritonitis carried the least risk to life of these three patients, i.e., 23% as compared with 49% and 46% for wound infection and bowel fistula, respectively.

Of the various synthetic meshes used, the author's experience was limited to Marlex[®] in 23 and prolene in 101 (Table 12). Marlex had twice the incidence of postoperative wound sepsis, almost six times as many associated bowel fistulas, and less than one-third as many successful skin graft takes for cover. Even more striking was the fact that Prolene[®] mesh could be retained permanently once skin closure had been obtained in 21 patients, or one-third of the 63 patients where such had been planned. By contrast, Marlex mesh required removal in all but two patients in whom it had been inserted. Finally, ease of removal was dramatically different between the pliable, smooth Prolene fabric and the stiff, textured Marlex mesh.

Deaths

Three of the 45 deaths occurred in the immediate postoperative phase as a result of profound hemorrhagic shock (Table 13). Three other deaths were unrelated to mode of wound care. However, 39 deaths were directly due to some complication of abdominal wound management. Sepsis accounted for 33 deaths, while intestinal fistula was primarily responsible for death in the remaining six patients.

Discussion

Major defects in abdominal wall substance pose three basic problems.^{13,14} First, there has been varying depth and extent of abdominal wall infection,^{3,5,10,11,14} injury,^{3,4-7,9,11,15} or tumor infiltration^{14,15-17} which now requires radical excision. At this stage, no thought of subsequent closure should ever influence the surgeon to be less thorough in his debridement or to accept less than adequate tumor resection. Patient survival must always be the paramount consideration.

Secondly, the intra-abdominal visceral disease or injury must also be appropriately managed. If inflammation is intense, contamination by bowel contents has been significant, or polymicrobial peritonitis has become well established, primary intestinal repair or anastomosis takes on an added risk. No longer does the presence of a proximal intestinal vent bode the catastrophe it once was held to represent, as intravenous total parenteral nutrition can now provide all of the necessary foodstuffs both for sustaining life and for healing wounds. Even the most tenuous electrolyte balance can now be maintained.

Because of difficulty in the control of intestinal efflux from loop constructed enterostomies and colostomies, a primarily matured end-stoma is preferred. Sterile enterostomy bags can then be fitted immediately to the abdominal wall before the patient leaves the operating room. In this way, such proximal vents are easily isolated and thereby will avoid the disastrous consequences of a bowel fistula located in the depths of an infected wound.

Finally, when necrotizing infection or multiple organ system trauma is responsible for the abdominal wall

TABLE 9. Management of Defects Due to En Bloc Resections

	Number of Patients	Wound Sepsis/Necrosis	Peritoneal Sepsis	Bowel Fistula	Died of Complications	Died of Other Causes
Primary closure	2	2	1	1	1	—
Gauze pack	1	—	—	—	—	—
Pedicled flap	7	5	—	—	—	1
Mesh prosthesis	1	—	—	—	—	—
Total patients	11	7	1	1	1	1

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TABLE 10. Complications of Wound Management/Death Due to Complications

	Number of Patients	Wound Sepsis/Necrosis	Peritoneal Sepsis	Bowel Fistula	Died of Complications	Mortality Rate (Per Cent)
Primary closure	13	13	7	4	11	85
Gauze pack	15	3	2	1	1	7
Pedicled flap	12	10	2	1	2	17
Fascial prosthesis	124	37	19	7	25	20
Operative death	3	—	—	—	—	—
Total patients	167	63	30	13	39	23

defect, intensive supportive care of associated disease states, such as diabetic ketoacidosis and end-stage renal failure, demand at least an equal therapeutic effort. Often, a team of specialists from many disciplines of medicine may be required. Nevertheless, the surgeon must remain the primary physician in charge, for it is wound management and wound complications which exert the greatest influence on patient outcome.

Closure of the abdominal wall under excessive tension has regularly failed because of subsequent tissue disruption and serious wound infection.^{3,4} In fact, fatalities are more often the result of choosing this method to gain closure than any other factor.⁵ The pedicled flap does eliminate tension,^{3,16,17} yet a less than ideal blood supply as well as greater exposure of subcutaneous surface to significant polymicrobial contamination will lead to an unacceptably high rate of wound complications and even to an occasional septic death.

Use of a gauze pack for such closure has appeared to provide a reliable alternative.⁸ If the wound is small, the pack itself can prevent abdominal evisceration. However, in cases where there is too great a gap between the abdominal side walls, insertion of a sheet of synthetic mesh to bridge the defect will maintain visceral position within the abdomen proper.^{3,4,7,9,11-13} The same technique of gauze dressing is still used, but now it is placed directly on top of the synthetic mesh. Accordingly, daily dressing changes are required, just as before, until the wound has developed granulations on bowel surface, as well as on incision side walls, thus indicating adhesions will avert evisceration and a

wound bed acceptable for skin grafting has been achieved.

In selection of a fascial substitute, certain fabric characteristics appear to be crucial.^{1,9,13,18} The substance should be: 1) pliable so as to preclude erosion into major structures, 2) inert, thereby avoiding a greater inflammatory response, 3) porous so as to allow free drainage of exudate, and 4) fiber resilience sufficient to maintain mesh integrity and thus to offer some potential for permanence. Marlex is stiff and exhibits fiber fatigue, while sheets of Silastic are not porous.^{1,13} To date, Prolene mesh has appeared to be the only fabric that meets all of these criteria.^{1,13}

Final restoration of abdominal wall structure should never be attempted until all intestinal vents have been closed.⁸ At a subsequent operation, the skin-covered scar which bridges the fascial defect is excised, another fascial prosthesis is inserted (preferably Prolene mesh), and skin with soft tissue is brought in as

TABLE 12. Comparison of Synthetic Meshes

	MARLEX	PROLENE
Patients	23	101
Wound sepsis	12	25
Intestinal fistula	4	3
Skin grafted	15	29
Acceptable take (>80%)	3	21
Planned mesh retention	19	63
Erosion into bowel/skin	3	1
Late removal	17	42
Difficult removal	16	7

TABLE 13. Cause of the 45 Deaths

Cause of Death	Number of Patients
Wound/peritoneal sepsis	33
Intestinal fistula	6
Hemorrhagic shock	3
Cerebral thrombosis	1
Pulmonary embolism	1
Alcoholic hepatitis	1

TABLE 11. Complications of Wound Management

	Number of Patients	Died	Mortality Rate (Per Cent)
Wound sepsis/necrosis	63	31*	49
Peritoneal sepsis	30	7*	23
Bowel fistula	13	6	46
Total patients	65	39	60

* Five patients died of both wound and peritoneal sepsis.

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a pedicled subcutaneous flap or as a formal myocutaneous flap to provide surface closure.⁸ The donor area from which the flap has been rotated is closed at the same time by application of a split-thickness skin graft.

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DISCUSSION

Dr. J. DAVID RICHARDSON (Louisville, Kentucky): In Louisville over the past five years we have treated over 40 patients with similar problems. We have had 31 patients survive.

(slide) The slide indicates the degree of infection seen in our 31 patients in whom we could not achieve fascial closure and subsequently placed polypropylene mesh. Basically, it parallels the experience that Dr. Stone presented. We excluded our tumor patients, and, as you can see, 29 out of 31 patients had contaminated wounds, 27 of the 31 patients had significant abdominal abscesses, and 23 had extensive fasciitis, prohibiting primary closure.

In terms of the immediate results, no patients eviscerated. There were no patients who actually required reoperation for fasciitis alone, if their initial operation was adequate. However, 23 patients did require at least one intra-abdominal operation, or repeat intra-abdominal operation, for persisting sepsis. And, again, the use of synthetic mesh allowed reoperations to be done with maintenance of at least a degree of abdominal wall integrity.

(slide) We have used primarily Marlex mesh, and have had significant late problems in patients in whom the mesh could not be completely removed with subsequent primary fascial closure. In nine patients in whom we did split-thickness skin grafting over the mesh, even when there appeared to be a very good granulation bed, all have had extrusion, three have had fistulas—one died as a result of fistula. Similarly, for patients in whom we tried to let the wound heal by secondary intention, there was a fairly significant rate of continuing wound problems. We have now had four patients in whom we have done elective full-thickness coverage, using musculocutaneous flaps, and it appears in that small experience that this is the way to go.

(slide) This is a patient who had a shotgun wound with a 9 cm defect, massive contamination by bowel and bladder injury. We closed the wound with Marlex to restore abdominal wall integrity after repairing intra-abdominal lesions. The bladder injury was closed with a suprapubic tube and brought directly through the mesh, since that appeared to be the most convenient way to drain the patient.

(slide) This shows, after the bladder has healed, the suprapubic cystostomy is removed and the patient has a good granulating bed. The patient still needs some type of synthetic coverage to provide abdominal wall integrity. (slide) In this particular case, we chose a myocutaneous flap. Rather than grafting that bed, we chose a myocutaneous flap even though the bed appeared adequate for grafting based on the lateral circumflex femoral artery. The patient healed well, as have our other four patients in which this has been done.

This is done electively, after contamination has been controlled, and it does seem to yield better long-term results.

I think the point that Dr. Stone made, that we would emphasize, in a fairly large experience in a five-year period, is that even in the face of significant contamination this synthetic material is well tolerated, but there are significant wound problems that must be dealt with at a later date.

Dr. ROBERT M. MILLS (Memphis, Tennessee): Dr. Stone has addressed a problem which few people write about, probably because their results are so poor. Even in Dr. Stone's hands, with the infectious types—that is, the necrotizing cellulitis and sepsis—the mortality rate was around 60%.

Although the use of fascial prostheses brought this down to about 20%, with the synthetic meshes the incidence of wound sepsis was still fairly high. With Marlex it was 50%; with Prolene, about 25%. A number of these developed fistulae, and necessitated eventual removal of the mesh.

In such cases, we have used a method for many years which is so simple I hesitate to mention it before this group, but, other things equal, it works most of the time. It's based on the principles of, first, containing the viscera, and, second, permitting adequate drainage. Assuming the source of infection is controlled, and adequate nutrition is maintained, granulation tissue will develop, wound contraction will occur, and grafting will be possible, with final repair of the defect at a later date.

(slide) This is a diagram of the method. The defect is covered with a simple sheet of polyethylene plastic and filled with gauze fluff or cotton balls. Several abdominal pads are placed over this and the whole dressing is secured with a Velcro-lined binder wrapped around the whole torso, fairly tightly.

This is the principle of the Mikulicz pack, which we've all used for the perineal defect of an abdominoperineal resection. It permits drainage by capillary attraction and at the same time it contains the viscera and does not stick to them. This is changed every day or two, permitting the access of air into the wound, which I think is very helpful.

We had such a case recently. The patient had a gunshot wound which severely traumatized his transverse colon, which had to be resected. A proximal end colostomy was performed and the distal end was closed and dropped back. He also had a through-and-through wound of the duodenum, which was repaired.

Around the ninth day after operation, he developed a necrotizing cellulitis, which was opened and drained. Following this multiple

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debridements were necessitated, leaving a defect of approximately 25 x 14 cm.

(slide) This shows the defect about one week after we started this procedure. You can see, his transverse colon is gone. This is the stomach; this is the small intestine.

(slide) This is the binder used to cover the dressing.

(slide) And twelve days later nice granulations have formed. The wound has contracted, so it's much smaller than it was originally.

(slide) This was grafted on the thirtieth day after operation, and a definitive repair will be done later.

I'd like to ask Dr. Stone one question. Is it possible by sewing in the prosthesis that free drainage is prohibited, with the subsequent development or the persistence of sepsis? And is it possible that the mesh, becoming occluded, keeps the air from getting to the wound, and could that play a part also?

Dr. BOYD W. HAYNES, Jr. (Richmond, Virginia): I simply would like to add a few comments out of our experience, which agrees, basically, but offers a different perspective. First, when presented with a wound of the abdominal wall that cannot be closed because of infection or dehiscence, the primary objective should be placement of a mesh (Marlex, Prolene) in order to prevent evisceration and to facilitate primary wound healing.

(slide) This can be best and most simply achieved by putting the mesh in, having it granulate, and then covering it with a split graft. The objective is not a permanent mesh, but a temporary mesh, which then will be, at the proper time, removed, in order to provide the necessary wound treatment to provide a solid abdominal wall.

This patient will exemplify such ideas. You see the stoma—and Dr. Stone spoke of stomas. These are widely separated, and therefore pose a problem in eventual closure. But here is the basic wound, which had a wide dehiscence, with a Marlex mesh under it, and a split graft over the top.

Once the graft healed, the patient was discharged and followed over a long period of time, looking for the development of wound maturity, so that the eventual removal of this graft and the mesh could be carried out, and closure of the wound obtained.

This can be done, as I think all of you are aware, with extensive wounds of the abdomen, extending lateral to the rectal sheath, provided good, soft wounds are obtained before the final closure is attempted.

In some instances, closure of the colostomy was impossible prior to the definitive closure of the wound. If the colon is well prepared, even though the central transverse colon may be missing one can combine primary closure of the colon with primary repair of the abdominal wall.

I think these are important concepts which simply add to what Dr. Stone has demonstrated for us.

Dr. H. HARLAN STONE (Closing discussion): With respect to the experience that Dr. Richardson cited, note, that 23 out of 24 of their patients had intraperitoneal sepsis, the mesh sometimes can be put to good use. These patients can be turned; one, and often times they may spontaneously drain intra-abdominal occultations through the mesh. Frequently, though, it does require reoperation, and if the mesh is in place and the adhesions have not forced it to any great depth, one can merely cut into the mesh, drain the infection, and then sew the mesh back up with a running suture of Prolene. It makes the whole procedure fairly simple.

The myocutaneous flap is probably the only flap to consider for use in these infected wounds. Dr. Jurkiewicz and his people have been most helpful in aiding us in the reconstruction of the abdominal wall of these patients. We prefer the tensor fascia lata flap, particularly for the lower abdomen. It has really been a lifesaver in many patients.

Dr. Miles, we have had a little difficulty in maintaining bowel within the abdomen when we have used a binder. It has been an especially great problem for the larger defect.

The mesh has provided excellent drainage of infection through the interstices. With solid sheets, we found that there would be poor to no drainage. With mesh, good drainage can be assured for up to seven days. Beyond that, patients vary as to when the intraperitoneal adhesions become too solid.

Dr. Haynes, we have tried to carry out colostomy closure before doing definitive repair, if such was later required. However, there are cases, as you point out, where this is impossible. For example, with twin stomas, there may be one in the right flank and one in the left flank. With a midabdominal defect, there is no way the tube can be brought together without reconstruction of the abdominal wall at the same time.

I want to stress, though, that we have found that it is most important to use Prolene rather than Marlex. Marlex creates many problems, while Prolene has been so much easier to work with.

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Comparison of Prosthetic Materials for Abdominal Wall Reconstruction in the Presence of Contamination and Infection

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Abdominal wall defects resulting from trauma, invasive infection, or hernia present a difficult problem for the surgeon. In order to study the problems associated with the prosthetic materials used for abdominal wall reconstruction, an animal model was used to simulate abdominal wall defects in the presence of peritonitis and invasive infection. One hundred guinea pigs were repaired with either polytetrafluoroethylene (PTFE) or polypropylene mesh (PPM). Our experiments included intraoperative contamination with *Staphylococcus aureus*. We found significantly fewer organisms ($p < 0.05$) adherent to the PTFE than to the PPM when antibiotics were administered after surgery, as well as when no antibiotics were given. In the presence of peritonitis, we found no real difference in numbers of intraperitoneal bacteria present whether PTFE or PPM was used. In all instances, the PTFE patches produced fewer adhesions and were more easily removed. From these experiments, it appears that PTFE may be associated with fewer problems than PPM in the presence of contamination and infection.

SYNTHETIC MATERIALS have been used to replace and reinforce the abdominal wall for many years.^{1,2} The necessary chemical and physical properties of an abdominal wall prosthesis include: (1) hypoallergenicity; (2) a lack of proven carcinogenicity and inflammatory response; (3) the ability to withstand sterilization; (4) the ability to not be modified by body fluids; (5) the ability to not induce a foreign body response; and (6) adequate strength.^{3,4} Many materials have been compared on the basis of strength⁵ and histologic tissue response;⁶ however, few investigators have studied the properties of different prosthetic materials in the presence of bacterial contamination or overt infection.

The most widely used material for abdominal wall replacement and reinforcement during hernia repair is polypropylene mesh (PPM) or Merilex.⁷ In 1976, we undertook a clinical study of polypropylene mesh and

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noted certain characteristics that caused difficulties in the presence of infection.⁸ Since then, microporous polytetrafluoroethylene (PTFE), or Gore-Tex⁹, has gained widespread use as a vascular prosthetic material⁹ and has demonstrated satisfactory tissue acceptance, ingrowth, and strength. In our present study, we compared PTFE to PPM for abdominal wall replacement in the presence of graded bacterial contamination.

One goal of this study was to compare the number of bacteria found on both PTFE and PPM after intraoperative contamination, similar to what might occur during elective ventral hernia repair. In a second series of experiments, we performed abdominal wall replacement in the presence of peritonitis. The bacterial concentration of intraabdominal fluid was obtained in an effort to determine if PTFE decreased peritoneal drainage in comparison to PPM in the presence of peritonitis, as has been suggested by others.¹⁰ Qualitative assessments were made as to the degree of adhesion formation produced by each prosthetic material.

Materials and Methods

Experimental Bacterial Contamination

Adult female Hartley guinea pigs, weighing 350–400 grams, were anesthetized with ketamine (37.5 mg/kg) and xylozine (5 mg/kg) administered intramuscularly. Using sterile technique, a 4-cm midline skin incision was made to the linea alba, and the surrounding subcutaneous tissues were dissected free from the abdominal wall. A 2-cm² full-thickness segment of midabdominal wall was excised. The defect was repaired by suturing a 2-cm² patch of prosthetic material to the abdominal wall margins with 4-0 running polypropylene suture placed 4 mm from the edge of the defect. Forty animals

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TABLE 1. Adhesion Formation Indexes for Groups A-D

Group	PTFE*	PPM†	n
Group A (contamination without antibiotics)	1.8 ± 0.1	3.9 ± 0.1	20
Group B (contamination with postoperative antibiotics)	1.2 ± 0.2	3.1 ± 0.2	20
Group C (contamination with preoperative antibiotics)	1.4 ± 0.2	3.7 ± 0.3	20
Group D (peritonitis)	1.5 ± 0.2	3.8 ± 0.1	16
Controls	1.0	3.0	20

* Each value or adhesion index is determined from the average of the qualitative numerical grade assigned to each animal within the individual groups at the time of patch removal (\pm SD). 1 = no adhesions; 2 = minimal adhesions; 3 = moderate adhesions; 4 = dense adhesions.
 † $p < 0.05$, $r = 1.06$ = Kendall's rank coefficient.

had abdominal wall reconstruction with polypropylene mesh (Marlex), and 40 animals had abdominal wall reconstruction with polytetrafluoroethylene soft tissue patch (Gore-Tex).

Prior to skin closure, 30 animals that were repaired with PPM and 30 animals that were repaired with PTFE received an injection of 10^8 *Staphylococcus aureus* in 0.5 ml phosphate buffered saline (PBS) on the surface of the prosthetic patch. The skin was closed over the patch with 4-0 interrupted dermalon sutures. The remaining 10 animals that were repaired with PTFE and the remaining 10 animals that were repaired with PPM received no bacterial challenge and served as noninfected controls.

The animals were housed individually, fed laboratory chow (Purina® #5025) and given water *ad libitum*. On the fifth day after surgery, the animals were sacrificed with an intracardiac injection of 1 ml of T61 Euthanasia Solution (Hoechst Pharmaceuticals, Somerville, NJ). The patches were immediately removed under sterile conditions and placed in a glass mortar containing 5 ml of PBS. The patches were homogenized for 5 minutes, and the homogenate was serially diluted, plated on nutrient agar, and incubated overnight at 37°C. The bacterial counts obtained were expressed as the logarithm of the number of organisms per square centimeter of prosthetic patch.

At the time of sacrifice, all wounds were examined for qualitative assessment of adhesion formation by a

classification of four grades: grade 1, no adhesions present; grade 2, minimal adhesions requiring very little blunt dissection; grade 3, moderate adhesions requiring aggressive dissection; and grade 4, dense adhesions requiring meticulous sharp dissection to free the prosthetic graft from the abdominal viscera. Each animal received a numerical assessment at autopsy for the degree of adhesion formation, and these values were subsequently averaged within each group with a resultant adhesion index for each group (Table 1).

The animals were placed in one of four groups: each group contained 20 guinea pigs, of which 10 were reconstructed with PTFE and 10 with PPM. Group A animals were contaminated with *Staphylococcus aureus* and received no antibiotics. Group B animals were contaminated with *S. aureus* and treated with an antibiotic (gentamicin, 8 mg/kg) administered intramuscularly 24 hours after implantation and every 12 hours thereafter until sacrifice. Group C animals were contaminated and given a single dose of antibiotic (gentamicin, 8 mg/kg) 1 hour prior to implantation. The remaining 20 animals were not contaminated and served as noninfected controls for the assessment of adhesion formation. Sensitivity of the *S. aureus* to gentamicin was confirmed by Bauer-Kirby disc diffusion techniques.

Experimental Peritonitis

Group D consisted of 20 animals that were injected intraperitoneally with 10^3 *Streptococcus faecalis*, 10^4 *Escherichia coli*, and 10^5 *Bacteroides fragilis* in 2 ml of 2.5% sterilized fecal solution. Forty-eight hours after injection, in the presence of fibrinopurulent peritonitis, the animals underwent abdominal wall excision and reconstruction as previously described for groups A, B, and C. Ten animals were repaired with PPM and 10 animals with PTFE. These animals received no antibiotics.

Five days after implantation, the animals were sacrificed and quantitative bacterial cultures performed on the peritoneal fluid and the respective patches. We chose this sampling period based on our observations in a pilot set of experiments, in which a high incidence of wound dehiscence and graft extrusion was observed after 5 days, producing spurious bacteriologic data. This pilot study was not included in our present study. The number of organisms within the peritoneal fluid was expressed as the logarithm of organisms per milliliter, and the bacterial counts from the prosthetic patched were expressed as the logarithm of organisms per square centimeter of prosthetic patch (Table 2). In groups A, B, C, and D, full-thickness, cross-sectional samples of intact graft or mesh were taken for histologic sampling from each animal.

TABLE 2. Quantitative Bacterial Cultures from Group D for Peritoneal Fluid and Prosthetic Material

	PTFE*	PPM†
Peritoneal fluid \log_{10} organisms/ml	6.0 ± 0.4	6.3 ± 0.5
Prosthetic patch \log_{10} organisms/cm ²	5.7 ± 0.6	6.1 ± 0.5

* Each value is determined from the average of the individual counts for each animal (N = 16) (\pm SD).

Results

Experimental Bacterial Contamination

There was very little qualitative difference in the appearance of the incisional wounds between those animals implanted with PTFE and those implanted with PPM in groups A, B, and C during the 5-day postoperative period. All wounds became erythematous and indurated, and a similar proportion of wounds in each group spontaneously drained purulent material.

At autopsy, all wounds had fibrinopurulent encasement of the prosthetic patch and frank pus between the patch and abdominal skin closure. In groups A, B, and C, the PTFE patches were significantly easier to remove than the PPM patches. The underlying viscera were consistently adherent to the PPM patches with grade 4 adhesions occurring in group A (Fig. 1). The adhesions surrounding the PTFE patches could easily be lysed with gentle blunt dissection. The adhesions attached to the PPM patches frequently required sharp dissection for removal. By creating an adhesion index from qualitative assessment at the time of patch removal, it was possible to show a significant difference between the PTFE and PPM groups ($p < 0.05$; $\tau = 1.06$ Kendall's rank coefficient) (Table 1). The wounds in the control group were similarly examined and fewer adhesions were found than in the infected groups. Even in the absence of infection, the PPM patches were much more adherent than the PTFE patches (Table 1). There was no bacterial growth found in the control patches. Comparison of the bacterial counts between the PTFE and PPM patches was statistically different in group A (Fig. 2). The PTFE patches contained 100-fold fewer organisms per centimeter squared than did the PPM patches ($p < 0.05$ Student's paired t test). In group B, the overall counts were less than in group A. The PTFE patches in group B contained significantly fewer organisms per square centimeter than did the PPM prosthetic group ($p < 0.05$ Student's paired t test) (Fig. 2). In group C, there was no statistical difference between the bacterial counts for the two types of prosthetic patch. The log₁₀ organisms per square centimeter for PTFE and PPM were 5.8 ± 0.6 and 6.4 ± 0.9 , respectively.

Histologic sampling revealed very little difference between animals reconstructed with PTFE and those reconstructed with PPM in groups A, B, and C. All specimens showed an acute inflammatory response with a large amount of purulent exudate.

Experimental Peritonitis

Animals in group D exhibited a generalized purulent peritonitis at 48 hours after injection of bacteria-fecal solutions. Bacterial cultures revealed all three of the



FIG. 1. PPM removed from an animal in group A at 5 days after implantation (top); PTFE removed from an animal in group A at 5 days after implantation (bottom).

inoculated organisms to be present. Fibrinous exudates were present on the viscera along with serosanguinous peritoneal fluid at the time of abdominal wall excision and reconstruction.

No subjective differences were noted in the skin surrounding the incision between animals repaired with PTFE and animals repaired with PPM. All wounds had less surrounding erythema and induration than those in groups A, B, or C. Two animals from the PTFE group and two animals from the PPM group died after the reconstructions. Death appeared to be related to sepsis as the animals had ruffled coats and crusting of both eyes prior to death.

At autopsy, the adhesions were significantly reduced in those animals implanted with PTFE. As in groups A, B, and C, the removal of PPM required sharp dissection,

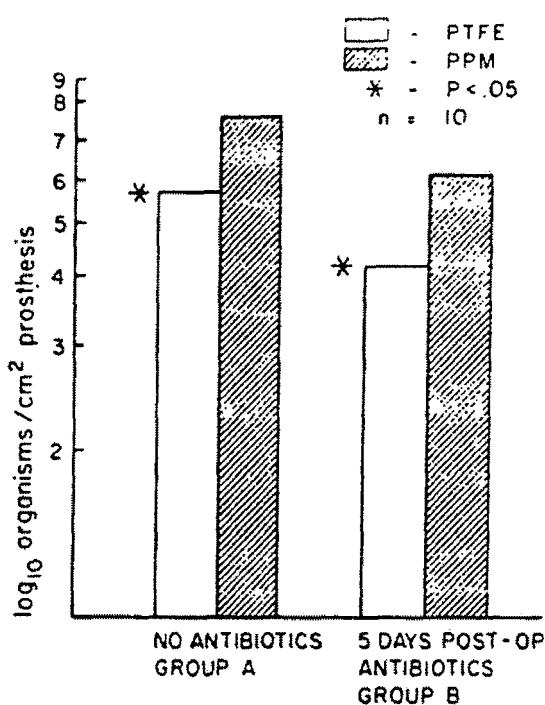
EXPERIMENTAL CONTAMINATION
(*S. AUREUS* 10⁸)

FIG. 2. Quantitative bacterial counts of the two different prostheses at 5 days after contamination.

whereas PTFE simply peeled out once the surrounding suture was cut (Table 1).

The amount of peritoneal fluid present at autopsy was similar for both prosthetic groups, varying from 0.15 ml to 0.2 ml. There were no significant differences between bacterial counts of the peritoneal fluid and the prosthetic patches for the two groups (Table 2).

Histologic sampling revealed very little difference between the two prosthetic materials. All specimens showed an acute inflammatory response with a large amount of purulent exudate present.

Discussion

Very little information is available regarding specific properties of prosthetic materials for abdominal wall reinforcement in the presence of infection. It was the purpose of this experiment to compare PPM and PTFE in two situations of simulated specific clinical problems

The study was designed to simulate contamination as it might occur while using these prosthetic materials for

elective abdominal wall reinforcement (i.e., herniorrhaphy). We chose *S. aureus* as the infecting organism because it is frequently associated with intraoperative contamination. Elek et al.¹¹ showed that, when foreign materials are present, fewer organisms are required to produce a clinical infection. The foreign material acts as an adjuvant by decreasing the number of bacteria necessary to produce an infection. Some materials seem to be more effective than others when used as adjuvants in infection.

In the first portion of this experiment, PTFE prostheses in groups A and B grew significantly fewer organisms after contamination than did the PPM patches. When antibiotics were administered after contamination, the overall total bacterial counts in each group were reduced; however, the PTFE prostheses continued to contain statistically fewer organisms. Surprisingly, when antibiotics were administered prior to contamination (group C), there was not as large a difference between bacterial counts for the two prosthetic materials. Although the PTFE patches continued to contain fewer organisms, the difference was not statistically significant, and the overall counts were greater than group B. Our experiments did not indicate that the "decisive period," as described by Miles,¹² affected our outcome. From our data, postoperative antibiotics produced lower bacterial concentrations per square centimeter than did a single preoperative dose, which suggests that postoperative, in addition to preoperative, antibiotics are indicated for abdominal wall reconstruction if contamination occurs.

It may be that PTFE is more resistant to the production of a clinical infection if contamination occurs intraoperatively. This seems to be a logical assumption since, in the absence of antibiotics or with antibiotics administered after contamination, the PTFE patches consistently had 100-fold fewer organisms per square centimeter than did the PPM patches (Fig. 2). Bacterial adherence is a complex phenomenon involving stereospecific interaction between bacterial ligands and receptor sites on the foreign body surface.¹³ The magnitude of adherence is related to the type of bacteria and foreign body involved in the interaction.¹⁴ Therefore, because of the microporous structure (30 μ) of PTFE and its decreased wetting properties, compared to the macroporous surface of PPM, PTFE may serve as a less hospitable nidus for bacterial adherence than does PPM.

Marlex (PPM) gained widespread use in clinical situations during the Vietnam War.¹⁵ However, there have been long-term complications associated with PPM that include fistula formation, draining sinuses, and mesh extrusion.^{8,16,17} A commonly ascribed basis for using PPM for acute abdominal wall reconstruction is that it

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may, by virtue of its porosity, allow macromolecular substances to drain from the infected peritoneal cavity. The use of a microporous material, such as PTFE, in this clinical setting has been questioned because of possible inhibition of peritoneal drainage. However, there is evidence that the peritoneal cavity is sealed and becomes impermeable to drainage within 12 hours even when PPM is used.¹⁸ This fact supports the finding by others¹⁹ that it is impossible to drain the entire peritoneal cavity in diffuse peritonitis. Because of this, we created an animal model to simulate abdominal wall defects in the presence of peritonitis or invasive infection. In our study, animals reconstructed with PTFE in the presence of peritonitis had the same mortality and intra-abdominal bacterial concentrations as did animals reconstructed with PPM (Table 2). As there was no statistical difference between bacterial counts and mortality, we concluded that PPM does not promote greater peritoneal drainage.

The bacterial counts obtained from the patches in the peritonitis model were similar, with the PTFE values slightly less than the PPM counts; there was no statistical difference (Table 2). This is somewhat at odds with the previous finding from the contamination model but may be due to a difference in adherence properties associated with gram-negative organisms compared to *S. aureus*.

The fact that PTFE reconstruction did not enhance mortality or increase intra-abdominal bacterial counts associated with peritonitis is an important finding in that it does not preclude the use of PTFE for abdominal wall replacement associated with invasive sepsis. This finding, along with significantly fewer adhesions produced by PTFE (Table 1), suggests PTFE may be as useful as, if not more useful than, PPM for acute abdominal wall reconstruction secondary to infection and traumatic abdominal wall loss.

The lack of differences in histologic findings between the prosthetic groups may be related to the short sampling time (5 days) and the presence of infection. Others²⁰ have shown a much more desmoplastic response to PPM than to PTFE; however, these studies performed histologic sampling several weeks after implantation and in the absence of sepsis.

In conclusion, PTFE produced less bacterial adherence in an intraoperative contamination model and created fewer adhesions in control wounds, contaminated wounds, and peritonitis. In addition, PTFE does not

appear to worsen the course of peritonitis when used as an abdominal wall prosthesis. From these experiments, it appears PTFE may be preferred to PPM in certain clinical situations; however, well-controlled clinical trials are required before the long and generally favorable experience with PPM can be discounted.

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DISCUSSION

DR. MARK M. RAVITCH (Pittsburgh, Pennsylvania): I have three or four options. I can discuss the paper presented in the abstract; I can

discuss the paper that was given so deftly and smoothly on this platform; or I can discuss the manuscript. As has already been suggested, no one of these bears any relationship to the others, and I can give my own paper.

There are a number of interesting things about it. To begin with, my principal reason for rising is because I have many, many times said there is no justification for using foreign materials to repair ventral hernias. I think that is an extreme position. I do think that natural materials—fascia lata, for instance—are better. The plastic surgeons have been swinging ever huge muscle masses with skin on them. I think that is very good. But there is a large field of usefulness for the foreign materials and, as Dr. Polk has said, the astonishing thing is that they can become infected, and one can have healing occur in spite of this. When those little bits of bumps turn up in the Marlex^{*}, coming through granulations, you can excise those little bumps and, if you are lucky, the rest of the Marlex will stay down. It is extraordinary how well they can do.

As for the relative virtues of the two materials, as I understand it from Dr. Polk, one of the great virtues of GoreTex[†] was that when you became disappointed with it, it was easy to take out. This reminds me of Dr. Dean Warren's prime advantage in his variety of portacaval decompression operation, about which we will hear for most of the rest of the afternoon, I am sure, and that is that if you are disappointed with it, it is so easy to take down.

I think that there is room for these materials, and I think, there is need for study, and I plan to use GoreTex the next time I have a guinea pig with a hernia.

I would like to ask Dr. Polk whether the number of bacteria still on the prosthesis is an appropriate end point, or whether he does not need to talk about ultimate healing of the abdominal wall.

I have enjoyed this paper. It has been a privilege and a pleasure to discuss it, and I hope Dr. Polk feels the same way about that.

DR. RONALD COY JONES (Dallas, Texas): Dr. Brown and Dr. Polk have developed a rather simple animal model that will allow evaluation of these types of material prior to evaluating them in the human. For a long time we have had a need for such materials. I see its use in two clinical settings: one is in the patient who has sustained a shotgun wound, as was demonstrated in the first slide, and the other is in the patient who has a serious necrotizing infection with loss of the fascia and muscle of the abdominal wall.

Salvage of skin by use of parallel incisions sometimes allows coverage of the prosthetic material. Often we tend to debride the overlying skin down to infection, and fail to realize that we could have made parallel incisions and saved skin which would prevent the necessity of skin grafting.

I would like to ask three or four questions of Drs. Polk and Brown. One concerns the concept of the decisive period of antibiotic administration. I believe their findings are contrary to those Dr. Burke presented several years ago. He demonstrated that if the antibiotic is not administered within a period of 3 to 4 hours following contamination, there is no difference in the inflammatory response when compared to antibiotic use. This is somewhat contrary to what was reported in this experiment. Burke's model used penicillin-sensitive *Staphylococcus* injected into the dermis of guinea pigs, and I think the peritonitis model which Dr. Polk has developed is somewhat different. Is this a comparable animal model in the presence of a foreign body?

The second question is if they know whether or not granulation tissue will form on this material; because if the skin is removed, then you would like to be able to skin graft.

Thirdly, I would like a comment about whether or not there was seroma formation beneath the skin when the skin is closed over the mesh. Does the material have to be removed?

There is no question that small bowel fistulas occur with Marlex^{*}, and it extrudes from the skin. I would assume that the GoreTex[†] would be preferable, because if you do have to remove it, it would certainly be easier than having to remove the Marlex, which usually has to be removed within a period of 5 to 7 days.

DR. H. HARLAN STONE (Baltimore, Maryland): Several years ago, I presented to this Society our experience with 167 patients who had acutely lost their abdominal wall in full thickness. (Slide) Of these 167 patients, major complications involving the abdominal wall wound,

the peritoneal cavity, or a bowel fistula occurred in 65 patients. The mortality rate was quite significant for each of these individual complications. Thus, I believe that this study is quite timely as it addresses the issues of infection as well as synthetic mesh left in the wound.

As Doctor Polk mentioned, they "tolerate" me as a visiting professor at the University of Louisville about every 3 or 4 years. It is usually prompted whenever Doctor Polk attempts a hernia repair. This is a patient in whom he did a groin herniorrhaphy. It is his third or fourth postoperative day. I do not know how many of you have had the urgent request to serve as an emergency visiting professor. I had the misfortune to be the emergency visiting professor at the University of Louisville that particular year. I was impressed by the not too considerable amount of necrosis still present in the wound. This patient ended up with a hernia being repaired with mesh. I am certain that is what prompted the present study.

Survival of these patients is absolutely dependent upon radical, aggressive surgery, and replacement of the resultant defect with some form of mesh to prevent bowel protrusion.

(Slide) Unfortunately, when one makes suggestions at the University of Louisville, only a small amount of what is said ever reaches the ears of the chief. There is quite a difference between Marlex^{*} and Prolene mesh. They are both polypropylene, but one is exceedingly stiff, creates considerable difficulty at removal, and is very prone to cause bowel fistula. That is why we abandoned the use of Marlex. Our results were unacceptable, just as they have demonstrated in these guinea pigs. Prolene, on the other hand, has a smooth fiber, is more easily removed, is pliable, and seldom causes bowel erosion.

Finally, I want to congratulate Doctor Brown for his hard work in the laboratory, and Doctor Polk for his usual outstanding presentation of someone else's material.

DR. WILLIAM D. JOHNSTON (Nashville, Tennessee): I rise to ask one question, which is related to an interest that I have had in this subject, electively as well as in trauma and in infections. I was with Dr. Gene Bricker while he was working on the development of an absorbable mesh to use electively in radical pelvic surgery to immediately create a pelvic floor and for the purpose of use in infected wounds and post-irradiated wound problems with or without infection. He had difficulty convincing any of the suture companies to undertake the project because they did not feel that it would be profitable.

This fall a Vicryl Mesh[‡] appeared on the market. I have used it only once, 3 months ago, which is too short a period of time to know how successful it was in this one case. But I raise this question because Vicryl Mesh is not recommended as the sole replacement of a defect. It is recommended as an additional support to other tissues used to repair a defect.

My question is twofold: (1) Have you used this yet and, if so, what has been your experience with it? and (2) If you have not used it, what are your thoughts about using this absorbable mesh in these horribly infected cases with the plan of using a permanent mesh later, if necessary, for a late hernia?

DR. PAUL H. JORDAN, JR. (Houston, Texas): These are indeed very difficult problems, and I am sure that almost everybody will have their own way of handling these kinds of wounds. I would just like to suggest one possibility that worked well for me. Marlex^{*} with a sheet of silastic on one side was used. This provides strength for the abdominal wound and the silastic prevents adhesions between the intestines and the Marlex.

DR. GREGORY L. BROWN (Closing discussion): I would like to thank our discussants for their insightful and thoughtful comments, which I will try to answer.

First of all, Dr. Jones, we did see seroma formation in some of the animals, but there was no real difference that we could distinguish between the two prosthetic groups. As far as how well PTFE supports granulation tissue, there is unpublished data for noninfected wounds, which I suppose could be extrapolated to our experimental model.

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which shows PTFE supports granulation tissue. Again, that is very tenuous data.

I cannot really answer whether GoreTex^{*} has to be removed immediately in the presence of infection. As far as I know, this is the first *in vivo* study of the use of the GoreTex soft-tissue patch in the presence of infection. Obviously, there have been a limited number of clinical trials using GoreTex on elective herniorrhaphies, but as far as in acute situations, especially with contamination, I do not know what the answer to that will be, and I think the conclusion will have to await clinical trials.

Very interestingly—and this was a surprise to us—the prophylactic antibiotics in the contamination model did not, microbiologically, behave as well as did those patches that received postoperative antibiotics. The only postulate that I can, at least theoretically, explain this with is in relation to the work of some 30 years ago by Miles, Miles, and Burke. That study was not performed in the presence of a large foreign body, and because of the size of this foreign body relative to the animal, the *devisure period*, as we know it or think of it, may not be valid. If intraoperative contamination does occur, especially in an elective situation, with preoperative antibiotics on board, it may be reasonable to consider giving a full 5-day course of postoperative antibiotics, based on what we have shown here. I have no clinical data to back that up.

Dr. Rayitch, I want to thank you for your comments. I think that your suggestion about the end point being complete healing is a very good one. Our 5 days were not chosen arbitrarily. We did a series of pilot experiments and found that following the animals longer than 5 days produced a high incidence of wound dehiscence and graft extrusion, which resulted in exclusion of those animals from the study.

Dr. Stone, I want to thank you for your comments concerning your frequent visits to Louisville. The reason we chose GoreTex^{*}, and not prolene, was that of all prosthetic materials there are probably more people walking around with GoreTex than any other, and as you know, in the past decade we have seen very good results using GoreTex as a vascular prosthesis. In addition, there is very little data using PTFE in this experimental or clinical situation.

Dr. Johnson, we personally do not have any experience with Vieryl^P. However, there have been experiments performed that revealed decreased bursting strengths of abdominal reconstruction of wounds and, as to the question you raised, the adhesion indices were higher with that material.

With the materials being so similar in these experiments, cost may be a factor, and though we do not have detailed information about it, PTFE may be more expensive than PPM. I would like to take this opportunity to thank the Association for allowing us to present this paper.

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Polypropylene Mesh Closure of Infected Abdominal Wounds

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The management of extensive abdominal tissue loss in the presence of intraabdominal infection or wound dehiscence challenges the surgeon's ingenuity in wound care. Radical debridement and primary fascial closure may be impossible due to tissue loss or extensive bowel edema. The use of a synthetic mesh to bridge the fascial defect and maintain the integrity of the abdominal cavity may initially appear to be an attractive alternative to simply leaving the viscera exposed. However, this report and review of the literature document the frequent complications and high morbidity associated with this technique. An overall complication rate approaching 80% can be anticipated if polypropylene mesh is used in this emergency situation. Two modifications of wound care appear to markedly diminish the incidence of

serious complications. Covering the mesh with full-thickness skin or muscle flaps in the early postoperative period, or removing the mesh at the earliest time conducive to fascial closure (within 2 weeks) reduced the overall complication rate from 55% to 15% in this review. However, it is often impossible to predict which patients will be amenable to early mesh removal, and full-thickness coverage of a persistently infected wound is usually doomed to failure. Despite the occasional usefulness of these modifications, this review suggests that polypropylene mesh in the emergency setting has an unacceptably high complication rate, and alternative methods of wound care in these complex situations should be considered.

THE CLOSURE OF LARGE infected abdominal wall defects after traumatic tissue loss or necrotizing fascitis is a complex surgical problem. The primary goal in the management of these complex wounds is patient survival, with eventual restoration of the boundaries of the abdominal cavity. However, debridement and primary fascial closure is often impossible without unacceptable tissue tension. As a result, a number of elaborate wound care techniques have been suggested, including rotational myocutaneous flaps, leaving the wound open to close by secondary intention, and bridging the fascial defect with synthetic mesh.¹⁻⁵ Each of these methods have inherent problems and limitations. The risk of rotational flap death in the presence of a wound infection is prohibitively high.⁶ If the wound is left open and granulation tissue is allowed to form, the complications of bowel fistula, fluid, and electrolyte shifts, prolonged hospitalization, and difficult nursing

care can be anticipated.^{7,8} An absorbable synthetic mesh (polyglactin 910) has been suggested for these wounds, but experience with its use is currently very limited.

Polypropylene mesh (Marlex, PPM) has been proven safe and effective in the closure of clean, elective hernias. Its use has subsequently been extrapolated to patients with large infected abdominal wounds.⁹⁻¹⁰ The perceived advantages of PPM in this situation are its ease of use, ready availability, inherent strength, and relative nonreactivity. This purpose of this article is to review our institution's experience with polypropylene mesh (PPM, Marlex) in the closure of infected or dehisced midline abdominal incisions following an intraabdominal catastrophe and to present a review of the available literature concerning PPM use in this situation.

Materials and Methods

Over a 3-year period, five patients were identified in whom PPM was used to close the abdomen following ceilotomy for intra-abdominal sepsis. The medical records were reviewed for demographic data, underlying medical illness, and details of wound management.

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Operative indications and the rationale for PPM use were recorded. The technical aspects of the surgery were noted including mesh size, location, and suture technique. The postoperative dressing regime was noted. The postoperative course was reviewed for complications, specifically skin or tissue loss, bowel fistula, intra-abdominal or subfascial abscess, dehiscence, and need for reoperation. The time to eventual wound closure was noted, as was length of hospital stay and mortality.

The study group consisted of four women and one man, ranging in age from 20 to 71 years (mean, 45 yrs). Two patients were morbidly obese. All patients had undergone at least two previous celiotomies prior to PPM placement. The first abdominal exploration was for blunt trauma (2), perforated cecal diverticulum (1), gastroplasty (1), or hemorrhagic pancreatitis (1). The second operation was for drainage of intra-abdominal abscess in all cases. Subsequent operations were for continued abdominal sepsis or wound dehiscence. Polypropylene mesh was placed at the third operation in four patients and at the fourth operation in one patient. Primary abdominal wall closure was impossible in all patients due to bowel edema and abdominal wall tissue loss.

Results

The average amount of PPM placed was 200 cm². Mesh was secured with 0-polypropylene in a horizontal mattress fashion in all patients. The skin was never closed, and all wounds were packed open with saline soaked gauze, changed every 6-8 hours. Complications directly related to PPM placement occurred in four (80%) patients: a small bowel fistula developed in four patients,

and a wound dehiscence also occurred in one (Table I). Three of these four patients eventually recovered, and one died. One patient (20%) had a relatively uncomplicated recovery following PPM placement, with granulation tissue rapidly forming and split-thickness skin graft coverage successfully performed 3 weeks after PPM placement.

All four patients with complications of PPM placement eventually required removal of the mesh. Two of these patients sustained significant weight loss allowing mesh removal and primary fascial closure after bowel fistula had been operatively repaired. One patient with a bowel fistula and wound dehiscence underwent fistula repair, PPM removal, and wound closure with rectus rotational flaps. The fourth patient underwent mesh removal and fistula repair but eventually died of multi-system organ failure.

The average length of hospital stay was 4 months, ranging from 45 days to 6 months. Complications occurred between 14 and 487 days following PPM placement. Bowel function was slow to return after PPM placement, but a regular diet was tolerated 2 weeks postoperatively in 80% of the patients. One patient was maintained on total parenteral nutrition for 6 months prior to her death from multi-system organ failure. All four survivors eventually returned to their previous life-styles.

Discussion

The use of polypropylene mesh after wound dehiscence or fascial debridement arose out of favorable reports of PPM use in the elective repair of abdominal wall defects and the lack of an attractive alternative. The

TABLE I. A Summary of 14 Reports on the Use of Polypropylene Mesh in the Emergency Setting: Complications and Deaths

Authors (Ref. No.)	Patients (#)	Complications (% of all Patients)			Deaths (%)
		Fistula	Hernia	Extrusion	
Fitzgerald et al. ¹¹	1	0	0	0	0
Schmitt et al. ^{12,13}	3	0	0	0	0
Markgraf ¹⁴	3	0	0	0	0
Eng et al. ¹⁵	1	0	0	0	0
Pokornoy/Thal ¹⁶	1	0	0	0	0
Mathes/Stone ¹⁷	11	0	2 (18%)	0	2 (18%)
Gilsdorf/Shea ¹⁸	6	0	2 (33%)	1 (17%)	2 (33%)
Long et al. ¹⁹	2	1 (50%)	0	0	0
Voyles et al. ²⁰	31	4 (13%)	7 (23%)	14 (45%)	7 (23%)
Kendrick et al. ²¹	13	0	2 (15%)	0	5 (38%)
Wouters et al. ²²	20	4 (20%)	0	0	4 (20%)
Hedderich et al. ²³	10	2 (20%)	8 (80%)	0	2 (20%)
Chan/Esfahani ²⁴	21	14 (67%)	5 (24%)	0	6 (29%)
Jones/Jurkovich	5	4 (80%)	0	0	1 (20%)
Totals	128	29 (23%)	26 (20%)	15 (12%)	29 (23%)

No. 1

POLYPROPYLENE MESH CLOSURE

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TABLE 2. A Summary of 14 Reports on the Use of Polypropylene Mesh in the Emergency Setting: Eventual Method of Wound Closure

Authors (Ref. No.)	Patients (#)	Eventual Wound Closure (% of Total)			
		Primary Fascia	Spl.-Thick Skin Graft	Secondary Intention	Full-Thick Skin Graft
Fitzgerald et al. ¹³	1*	0	0	0	0
Schmitt et al. ^{14,15}	3	0	3 (100%)	0	0
Markgraf ¹⁶	3	2 (66%)	0	0	0 (33%)
Eng et al. ¹⁷	1	0	1 (100%)	0	0
Pokornoy/Thai ¹⁸	1	0	0	0	1 (100%)
Mathes/Stone ¹⁹	11*	0	5 (45%)	0	4 (36%)
Gilsdorf/Shea ²⁰	6*	1 (16%)	0	2 (33%)	2 (33%)
Long et al. ²⁰	2	0	2 (100%)	0	0
Voyles et al. ²¹	31*	6 (19%)	9 (29%)	6 (19%)	3 (10%)
Kendrick et al. ²²	13	0	0	0	5 (38%)
Wouters et al. ²³	20	15 (75%)	5 (25%)	0	0
Hedderich et al. ¹¹	10*	0	3 (30%)	5 (50%)	0
Chan/Esfahani ²⁴	21*	7 (33%)	5 (24%)	3 (14%)	0
Jones/Jurkovich	5	2 (40%)	1 (20%)	0	1 (20%)
Totals	128	36 (28%)	34 (27%)	16 (12%)	17 (13%)

*Reports with incomplete data regarding type of eventual wound closure.

first animal studies of PPM were reported in 1958 by Usher and Wallace.¹¹ A comparison of tissue reactivity to orlon, dacron, nylon, teflon, and polypropylene was performed by placing pellets of these materials intra-peritoneally in dogs. Polypropylene mesh and teflon were essentially nonreactive, as judged by lack of adhesions and foreign body reaction on histologic examination. A follow-up study compared PPM and teflon in the repair of large tissue defects in an animal model.¹² Teflon mesh induced less fibrous infiltration and tissue bonding when compared with the polypropylene mesh.

Usher reported the clinical use of PPM in the repair of ventral and inguinal hernias in 541 cases.^{13,14} The reported 5-year recurrence rate for these incisional and inguinal hernias was 10.9 per cent and 5.9 per cent, respectively. The ventral hernia group had a 15 per cent complication rate with six of 358 patients requiring PPM removal for infection. The inguinal hernia group had a complication rate of 4.3 percent, but none required removal of PPM for infection.

The excellent experience with PPM in the elective repair of large tissue defects prompted Schmitt et al. to use PPM in three Vietnam War soldiers who underwent emergency reoperation to close large, infected abdominal wounds, the first report of PPM use in this setting.^{15,16} These three patients developed no complications during the short 30-day follow-up period. The civilian use of PPM in the emergency setting was first reported by Fitzgerald et al. in 1964.¹⁷ The patient in this case was a victim of a shotgun blast to the abdomen with a large wall defect. Markgraf used PPM to repair abdominal wall defects in three patients with postoperative sepsis and extensive fascial debridement.¹⁸ These

patients did well postoperatively, but two required PPM removal within 10 months. The largest study of emergency use of PPM is from Louisville by Voyles et al. in which 31 patients had PPM placed for large abdominal wall tissue defects.¹⁹ This group of patients generally were quite ill, as judged by the overall mortality of 23 per cent and a complications rate of 81 percent. The most common complications were mesh extrusion, hernia formation, and enteric fistulization.

A total of 14 studies have reported on the results of 128 patients in whom PPM was placed following intra-abdominal sepsis, necrotizing fasciitis, wound dehiscence or traumatic tissue loss.¹³⁻²⁴ A summary of these reports of PPM use in the emergency setting are compiled in Tables 1 and 2. The overall complication rate seen with PPM use in the emergency setting is 55 per cent. The results reported in the current series (80% overall complication rate) corroborate these findings.

Several general observations about the use of PPM in the emergency setting can be made from the data summarized in these reports. Mesh extrusion occurred most commonly (44%) in patients with wounds healed by secondary intention. Mesh extrusion did not occur in wounds covered with full-thickness skin or muscle flaps. Ventral hernias occurred in all patients who underwent mesh removal without primary fascial closure. Enteric fistulization was the most common complication, present in 23 per cent of the patients summarized by these reports. The incidence of fistulization appears to be influenced by the type of coverage used over the mesh. Split-thickness skin grafting directly over granulating PPM resulted in a fistulization rate of 45 per cent. Healing by secondary intention had a fistulization rate

of 14 per cent. This complication was eliminated entirely by covering the exposed mesh with full-thickness skin or a muscle flap.^{19,26,29}

In general, smaller wounds that could be covered with full-thickness skin had fewer complications.^{19,23,24} Polypropylene mesh can often be removed and primary fascial closure accomplished in the early postoperative period. Early mesh removal and fascial closure dramatically diminishes the incidence of complications.^{14,19,22,23,27-29} Mortality is generally due to the primary disease process, not the complications of PPM use. However, specific morbidity (bowel fistula, mesh extrusion, lengthy hospital course) can be attributed to the use of PPM.

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ETH.MESH.06398883

<1>
Unique Identifier
93177896
Authors
Goonetilleke GC.
Institution
Base Hospital, Gampaha.
Title
Synthetic mesh in the repair of incisional hernia. [Review] ←
Source
Ceylon Medical Journal. 37(3):87-9, 1992 Sep.
MeSH Subject Headings
Abdominal Muscles/su [Surgery]
Adult
Aged
Aged, 80 and over
Female
Follow-Up Studies
Hernia, Ventral/ep [Epidemiology]
*Hernia, Ventral/su [Surgery]
Human
Male
Middle Age
Polypropylenes
Postoperative Complications/ep [Epidemiology]
*Postoperative Complications/su [Surgery]
Recurrence
Reoperation
*Surgical Mesh
Abstract
A series of 30 incisional hernia repairs with knitted monofilament polypropylene is presented. The recurrence rate was 3.3% (one patient). No patch has sloughed or required removal. There was one postoperative death. Synthetic mesh allows defects of any size to be repaired without tension with a low recurrence rate. [References: 11]
Registry Numbers
0 (Polypropylenes).

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HERNIA SURGERY

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INCISIONAL HERNIA

Thomas A. Santora, MD, and Joel J. Roslyn, MD, FACS

Incisional hernias are unique in that they are the only abdominal wall hernias that are considered to be iatrogenic. Incisional hernia continues to be one of the more common complications of abdominal surgical procedures and is a significant source of morbidity and loss of time from productive employment. Many of these patients will alter their lifestyles so as not to exacerbate their abdominal wall hernia. This change may reduce or even eliminate the potential for gainful employment. In this context, the economic impact of this disorder is incalculable. Moreover, the exact incidence of incisional hernias has not been well defined, although a number of reports in the literature suggest that the incidence is probably between 2% and 11%.^{1-14, 21, 22, 24, 40, 44} A number of predisposing factors have been identified that may be related to specific patient characteristics, an underlying pathologic process, or iatrogenic factors. From the surgeon's perspective, repair of incisional hernias is a commonly performed procedure.

The purpose of this article is to review our current understanding of the factors that predispose to incisional hernias in order to facilitate their prevention. We also describe the various surgical techniques that are available for their repair and highlight certain features of the unusual or more complicated hernias.

CLINICAL PRESENTATION

By definition, an incisional hernia represents a breakdown or loss of continuity of a fascial closure. This event typically is manifested from the patient's perspective by a bulge in an abdominal wall closure that is detected either visually or by direct palpation. Maneuvers that increase the intra-abdominal pressure, such as coughing, lifting the head or legs, or assuming the erect posture, typically make an incisional hernia more apparent. Most patients with small, uncomplicated incisional hernias will be asymptomatic or

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have only minor or intermittent complaints. Occasionally, patients with large hernias experience difficulty in bending, discomfort, even persistent abdominal pain, or intermittent intestinal obstruction, typically in the setting of adhesions to the hernia sac as opposed to incarceration of bowel at the level of the fascia. As with other hernias, incarceration or strangulation is much more common if the neck of the hernia defect is narrow.

The presence of an incisional hernia typically is readily apparent on clinical examination. However, in certain cases, ultrasonography, CT, or both¹⁻⁴ have been utilized to distinguish hernia defects from other abdominal wall processes that may present as mass lesions or be the source of pain syndromes.

Experience has suggested that incisional hernias can be noted either early after the index operation or many years subsequently. Numerous studies indicate that the majority of incisional hernias occur within the first postoperative year; however, most of these studies have limited follow-up and may therefore underestimate late hernia occurrence.^{1-4, 21, 22} In a 10-year prospective trial involving 337 patients, Mudge and Hughes²¹ showed that of the 62 patients who developed an incisional hernia, 56% did so after the first postoperative year, and 35% manifested their hernia after 5 years.

The explanation for fascial weakening and ultimately hernia formation in an apparently well-healed wound is not readily apparent. Urshel and coworkers²² state that in vitro preparations have shown that fascia under stress has increased synthesis of DNA and protein by fibroblasts and that this may continue for a long period of time. Those authors postulate that interruption of this process at a time remote from the apparent healing of the wound may lead to fascial weakness. Pollock and Evans²³ reported their prospective experience with 149 patients, the results of which indicated that early fascial separation may be predictive of subsequent incisional hernia. At the initial operation, metal clips were placed on either side of the fascia to mark the apposition, and an abdominal radiograph was obtained 30 days later. Of the 18 patients who ultimately developed hernias in the 43-month follow-up, 17 (94%) had demonstrable separation of the clips by more than 12 mm on their 1-month films. In contrast, only 1 of the remaining 131 patients, who had clip separation of less than 12 mm, ultimately developed a hernia. While this is an interesting study, the clinical usefulness of the information to the practicing surgeon remains to be defined.

Although data are hard to find, clinical experience suggests that most patients undergoing repair of incisional hernias do so only after the hernia has become of significant size or has been a source of important symptoms. The reasons for the delayed repair of so many incisional hernias probably derive from patient, as well as physician, attitudes. Recent data suggest that the timing of repair is often related to the severity of the patient's symptoms.²⁴ It also has been suggested that the timing of the repair and the associated delay often reported relate to the surgeon's knowledge of the recurrence rate for incisional hernias, which has been reported to be between 20% and 46%.^{15, 22, 23, 25}

Delays in repair can have clinical significance. In a retrospective study of 206 patients undergoing incisional hernia repairs, Read and Yonder²⁵ reported that the indication for repair in 17% of the patients was management of incarceration or strangulation. In a review of 3107 incisional hernia repairs, Heydorn and Velanovich²⁶ reported that the mortality rate was appreciably higher in patients undergoing repair of complicated hernias (1.1%) than in those individuals undergoing elective repair (0.3%).

Over the last several years, a number of new techniques for hernia repair

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INCISIONAL HERNIA 559

asionally, patients with large fort, even persistent abdominal ally in the setting of adhesions bowel at the level of the fascia. ation is much more common if

y is readily apparent on clinical ionography, CT, or both.^{2, 11} ts from other abdominal wall the source of pain syndromes. rnias can be noted either early sequently. Numerous studies occur within the first postoperative limited follow-up and may ^{12, 13, 14} In a 10-year prospective showed that of the 62 patients so after the first postoperative ¹⁵

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have been introduced. A growing experience with these innovative techniques suggests that the rate of recurrence after repair of an incisional hernia may in fact be reduced. The recognition of these data may prompt surgeons to repair incisional hernias at an earlier date, prior to the onset of severe symptoms.

PREDISPOSING FACTORS

A number of patient-related factors correlate with the propensity to develop incisional hernias. These factors include obesity, older age, abdominal distension, postoperative pulmonary complications, male gender, and the presence of jaundice.^{3, 19, 20} In addition, a number of specific factors that relate to the performance of the index operation have been noted to influence the likelihood of hernia development. These include wound infection, the type of incision and closure technique, and the type of suture material.

Wound infection

Numerous authors have suggested that the most common factor responsible for the development of incision hernia is a postoperative wound infection.^{2, 10, 21, 22} In a study of 1129 abdominal procedures, Bucknall and colleagues²³ reported that the index operation had been complicated by a postoperative wound infection in 48% of the patients who subsequently developed an incisional hernia. In this study, the presence of a postoperative wound infection was associated with a fivefold increase in the risk of development of a hernia (23%) compared with patients with uninfected wounds (4.5%). Similar findings had been reported earlier by Blomstedt and Welin-Berger.²⁴ Although most surgeons believe that prevention of a wound infection will in fact reduce the development of incisional hernias, this hypothesis has not been truly tested.

Incision Type and Closure Technique

Specific anatomic considerations suggest that transverse abdominal incisions should have less risk of a postoperative incisional hernia. The fascial fibers of the anterior abdominal wall lie in a transverse orientation. Therefore, a vertical incision would divide them, and suture closure of such vertical wounds would, in fact, place the suture material between the fibers. Contraction of the abdominal wall would cause laterally directed tension on the closure and might cause the suture material to cut through by separation of the transversely oriented fibers. In contrast, a transverse incision opens the fascia along the fibers such that suture closure places the suture material around fascial fibers. On contraction, the fibers are apposed, and the suture material would realize minimal laterally directed tension (Fig. 1). It is not surprising, therefore, that numerous studies suggest that incisional hernia is more common after midline as opposed to transverse incisions.^{2, 10, 21, 22} It should be noted, however, that these studies are uncontrolled for disease process, and so one must be cautious in such interpretations. Furthermore, as has been pointed out by Ellis and coworkers,¹⁹ the midline incision is the most versatile and is frequently used in urgent cases of hemorrhage, trauma, or abdominal sepsis. These conditions may have a greater influence on the development of incisional hernia than the type of incision used. This view is underscored by a prospective trial involving

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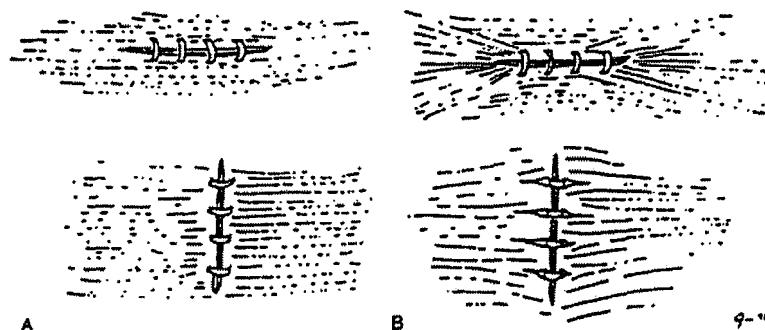


Figure 1. Comparison of the vertical and the transverse incisions. A, The resting state. B, During abdominal wall muscular contraction, laterally directed tension is created at each wound. Note the transverse incision is coapted during this process, whereas the vertical incision is challenged. This can result in suture pull-through.

non-urgent abdominal procedures, performed by Ellis and coworkers,¹⁴ which did not demonstrate any significant difference in the rate of hernia formation in patients undergoing midline, paramedian, or transverse incisions.

Other concerns related to the type of abdominal wall closure have to do with the use of continuous versus interrupted sutures (Fig. 2) and mass versus individual layer closure. Once again, although such arguments might be intuitively attractive, randomized studies have failed to demonstrate that any of these factors significantly alters the incidence of postoperative incisional hernia (Table 1).

Suture Material

Selection of suture material for abdominal wall closure is largely based on the individual surgeon's preference and experience. In a study reported in

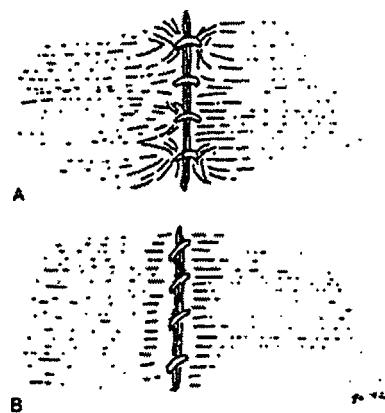


Figure 2. Comparison of the tension created by the two different suture techniques. A, In the interrupted technique, the tension is different at each suture. This may lead to fascial necrosis if tied too tight or poor approximation if tied loosely. B, The continuous technique disperses the suture tension along the length of the wound. The potential disadvantage of this technique is that the closure is reliant upon the integrity of this length of suture.

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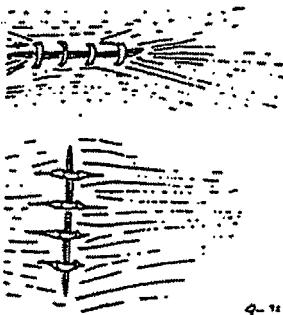


Fig. 1. Incisions. A, The resting state, rected tension is created at each suture process, whereas the vertical

Ellis and coworkers,¹⁴ which the rate of hernia formation transverse incisions. final wall closure have to do suture (Fig. 2) and mass versus such arguments might be used to demonstrate that any of postoperative incisional

closure is largely based on suture. In a study reported in

2. Comparison of the tension by the two different suture techniques. A, In the interrupted technique, tension is different at each suture. It may lead to fascial necrosis if tied too tight or poor approximation if tied too loosely.
- B, The continuous technique uses the suture tension along the length of the wound. The potential disadvantage of this technique is that the suture is reliant upon the integrity of this one suture.

Table 1. INCIDENCE OF HERNIA ACCORDING TO CLOSURE TECHNIQUES

Source	No. of Patients	Suture Material	Closure Method	Percent Hernia
Schoetz et al ¹⁵	186	PDS	Cont. mass	3
Lamont & Ellis ²²	699	Nylon	Cont. mass	6
Kendall et al ¹¹	108	Chromic & PDS	Layered	6.5
	104	PDS	Mass	6.7
Rubio ³⁴	1697	Polyester, Prolene	Layered	0.1
McNeill & Surgerman ²³	54	No. 28 wire	Int. mass	11.1
	51	Dexon Plus	Cont. mass	9.8
Deitel et al ¹⁶	42	Dexon Plus	Cont. mass	0
	42	Maxon	Cont. mass	9.5
Bucknall et al ⁵	684	Nylon	Mass	7.2
	164	Nylon	Rectus sheath only	8.5
	177	Catgut & nylon	Layered	5.1
	104	Dexon Plus	Mass	11.5
Goligher et al ¹⁸	107	Catgut	Cont. layered	14
	107	Catgut & internal nylon retentions	Cont. layered	4.8
	110	No. 28 wire	Int. figure-of-8	0.9

Abbreviations: cont = continuous, int = interrupted.

1952, Douglas¹¹ outlined the rate at which abdominal wall incisions regain their tensile strength. Data from this early study suggested that virtually no tensile strength is regained within the first week after surgery, but that there is a rapid increase in tensile strength over the next 70 days, with 90% being recovered by 1 year. During the early phase of wound healing, it therefore appears that the suture material does in fact play an important role in maintaining the integrity of the closure.¹⁴ Permanent suture has the theoretical advantage of maintaining its tensile strength through the lifetime of the wound. However, persistent suture has occasionally been a source of irritation and can act as a nidus for infection.

The ideal suture material should have three important characteristics: retention of high tensile strength, monofilament structure so that bacteria cannot hide within any interstices, and absorbable qualities so that the material is ultimately eliminated as a source of infection. A number of recently developed suture materials do have these favorable characteristics (Table 2). In a clinical trial of three methods of closure of laparotomy wounds, Goligher and coworkers¹⁸ demonstrated a 14-fold increase in wound breakdown when catgut sutures as opposed to interrupted stainless steel wire were employed. The use of wire has decreased dramatically in recent years because of the spread of the AIDS virus and the potential for incurring microlacerations of the surgeon's hands while tying. A number of clinical trials have compared the results with differing suture materials.^{3, 10, 11, 22, 23, 24, 25} Unfortunately, these studies are not matched for closure techniques or disease process; therefore, the lessons from this large number of studies are difficult to discern.

REPAIR OF INCISIONAL HERNIA

Overview

The success of an incisional hernia repair is dependent on a number of important factors. These include incorporation of healthy fascial tissue, which

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Table 2. CHARACTERISTICS OF SUTURES USED IN HERNIA REPAIR

Suture Material	Class	Raw Material	Composition	Tensile Strength (%) Remaining at 14 Days	Complete Absorption (Days)
Catgut	Absorb	Collagen	Twisted	0 (7-10 days)	70
Chromic catgut	Absorb	Collagen	Twisted	0 (21-28 days)	90
Dexon	Absorb	Polyglycolic acid	Braided	65	60-90
Vicryl	Absorb	Polyglactin acid	Braided	60	60-90
PDS	Absorb	Polydioxanone	Monofilament	70	180-210
Maxon	Absorb	Polyglyconate	Monofilament	75	180
Steel	Nonabsorb	Alloy of iron-nickel-chromium	Monofilament	100	No absorption
Silk	Nonabsorb	Protein fiber	Braided	100	2 years
Nylon	Nonabsorb	Polyamide			
Ethilon			Monofilament	100	Loses 15-20%/year
Nuronol			Braided	100	Loses 15-20%/year
Polyester	Nonabsorb	Polyester			
Mersilene			Braided	100	No absorption
Ethibond			Braided	100	No absorption
Prolene	Nonabsorb	Polypropylene	Monofilament	100	No absorption
Gore-Tex	Nonabsorb	ePTFE*	Monofilament	100	No absorption

*ePTFE = expanded polytetrafluoroethylene.

is brought together under minimal tension, and the avoidance of risk factors for hernia formation, which have been described.¹ Most important, perhaps, is the prophylaxis for wound infection. Houck and colleagues¹² suggested that the rate of wound infection after the repair of an incisional hernia was significantly greater than that seen in inguinal hernia repairs. This suggests the presence of occult infection in the incisional hernia wound. Furthermore, a prior wound infection in the incision was associated with a significantly higher rate of infection after the subsequent repair. For these reasons, a number of authors have advocated the routine use of antibiotics in patients undergoing ventral hernia repair.^{2, 4}

The size of the fascial defect and the appearance of the fascia should dictate the selection of the most appropriate method of hernia repair. The operation should be done with abdominal wall relaxation, suggesting that general or regional anesthesia would be most effective. The incision used in the repair should be based on the shape of the fascial defect and the location of the hernia. Usually, the surgeon strives to incorporate the old scar in the repair. The skin and subcutaneous tissue are dissected away from the hernia sac. Isolation of the healthy fascia can be done a few centimeters from the defect and the abdominal cavity entered through a virgin area. Another approach includes direct entrance into the peritoneal cavity through the hernia sac and identification of the fascia after the adhesions from the intra-abdominal organs have been taken down from the fascial defect. Ultimately, the superficial and deep surfaces of the fascia should be exposed for a distance of at least 3 to 4 cm along the circumference of the defect. The hernia sac, which typically represents attenuated fascia and peritoneum, usually is excised prior to repair. However, some authors advocate use of this sac for bowel coverage, especially when using a prosthetic material.¹³ Other authors^{14, 15} suggest incorporating the sac into a multilayered sutured repair.

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HERNIA REPAIR

Tensile Strength (%) Remaining at 14 Days	Complete Absorption (Days)
0 (7-10 days)	70
0 (21-28 days)	90
65	60-90
60	60-90
70	180-210
75	180
100	No absorption
100	2 years
100	Loses 15-20%/year
100	Loses 15-20%/year
100	No absorption

The avoidance of risk factors is most important, perhaps, is "alleagues" suggested that an incisional hernia was a repairs. This suggests the via wound. Furthermore, a with a significantly higher these reasons, a number of tics in patients undergoing

of the fascia should dictate hernia repair. The operation suggesting that general or incision used in the repair ect and the location of the the old scar in the repair. av from the hernia sac. et meters from the defect al area. Another approach through the hernia sac and intra-abdominal organs esily, the superficial and a distance of at least 3 to 4 hernia sac, which typically is excised prior to repair. bowel coverage, especially suggest incorporating the

Primary Closure Techniques

The likelihood of adequate and long-lasting repair can be increased by adherence to specific surgical principles. These include the proper placement of sutures in the fascia. Experience suggests that fascial sutures are best placed 1 cm back from the edge and 1 cm apart. This strategy provides for incorporation of healthy fascia on either side of the edge and should avoid protrusion of abdominal contents through the fascia by making small advancement of the stitches along the length of the wound. Fascial necrosis must be avoided; this can be achieved by apposing the fascia without tension and tightening the sutures only enough to bring the edges into approximation. The appropriate suture size should be selected so as to handle the anticipated tension of the wound and minimize the likelihood of fracturing of the suture. Finally, suture unravelling can be prevented by appropriate knot tying.

In many cases of incisional hernias with small to moderate-size fascial defects, fascial closure can be achieved by apposing the fascial edges and closing the wound in a continuous mass closure or by utilizing interrupted figure-of-eight or simple sutures. In addition, a modified Mayo technique, in which the fascial edges are overlapped, typically provides a satisfactory outcome.

When the fascial defect is sufficiently large to preclude the use of simple closure, a number of other primary repairs have been proposed and can be utilized at the surgeon's discretion. These measures include the use of internal retention sutures as advocated by Sitzmann and McFadden.¹¹ The Keel procedure, in which relaxing incisions are made in the lateral aspect of the anterior rectus sheath, thus allowing the medial aspect of the anterior sheath to be approximated in the midline (Fig. 3), is especially useful for large upper midline hernias.¹² This method is based on the observation that the strong posterior sheath in the upper abdomen reduces the potential for hernia formation in the area of the relaxing incisions. For midline defects in the lower abdomen, the

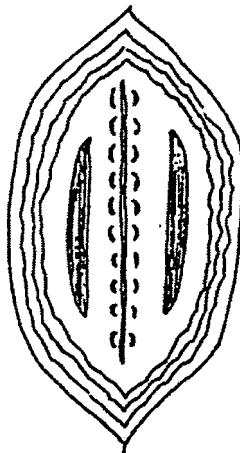


Figure 3. Maingot's keel procedure. Note the relaxing incisions in the anterior rectus sheath to facilitate the midline closure.

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Nuttall procedure has been reported to be quite effective.²² In this procedure, the lower aspect of the rectus abdominis muscle and its enveloping fascia are mobilized off the pubis and approximated to the contralateral bone. This maneuver provides anterior rectus sheath coverage for the lower midline defect (Fig. 4).

Mesh Repairs

The era of prosthetic material was initiated in the 1940s when the use of steel mesh was first advocated for the repair of incisional hernias.²³ These inflexible materials were difficult to use and resulted in considerable complications, including persistent sinus drainage, seroma formation, and fractured material with loss of tensile strength. The introduction of plastic prosthetics in 1958 rendered the metal meshes obsolete. In 1963, Usher²⁴ introduced knitted monofilament polypropylene (Marlex) mesh into clinical practice. Since that time, a number of other synthetic materials have been utilized for the repair of large incisional hernias. Each of these materials has unique characteristics that have appealed to surgeons (Table 3). Most studies suggest that Marlex mesh is still the most widely used prosthetic material for the repair of incisional



Figure 4. The Nuttall procedure. Local rectus abdominis flaps are used to correct a lower midline defect. (From Pollock R, Nyhus LM: Incisional hernias. In Schwartz SI, Ellis H (eds): Maingot's Abdominal Operations, ed 8. Norwalk, CT, Appleton-Century-Crofts, 1985, p 342; with permission.)

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effective.²³ In this procedure, and its enveloping fascia are he contralateral bone. This : for the lower midline defect

In the 1940s when the use of incisional hernias.²⁴ These led in considerable complications formation, and fractured fixation of plastic prosthetics in Usher²⁵ introduced knitted clinical practice. Since that been utilized for the repair of true characteristics that suggest that Marlex mesh is for the repair of incisional



Flaps are used to correct a lower hernia. In Schwartz SI, Ellis H (eds): *Primer of the Non-Century-Crofts*, 1985, p 342.

Table 3. CHARACTERISTICS OF PROSTHETIC MATERIAL USED IN HERNIA REPAIRS

Mesh	Material	Structure	Classification	Tissue Ingrowth	Adhesion Formation
Marlex	Polypropylene	Knit	Nonabsorb	Early, extensive	Mild
Prolene	Polypropylene	Woven	Nonabsorb	Early, extensive	Mild
Mersilene	Polyester	Woven	Nonabsorb	Early, extensive	Moderate
Gore-Tex	PTFE	Expanded	Nonabsorb	Minimal	Mild
Vicryl	Polyglycolic acid	Knit	Absorb	Mild-moderate	Moderate
Dexon	Polyglactin acid	Knit	Absorb	Moderate	Extensive

hernias,^{2, 24, 27, 28} although PTFE is gaining popularity because of its apparent reduced tissue reactivity. Most authors feel that absorbable mesh should not be used for permanent abdominal wall reconstruction because of the universal development of hernias in an animal study.²⁹ Mersilene (polyester) mesh also has been used extensively.^{12, 24, 31}

An ideal prosthetic material should retain a high intrinsic tensile strength and allow extensive tissue ingrowth. All of the woven or knitted permanent materials possess these desirable characteristics. Studies have demonstrated that PTFE resulted in less adhesion to underlying bowel than did Marlex mesh.^{2, 24} This is presumably because of the lesser fibrous ingrowth into the small interfibrillar spaces of the PTFE material. Although this may be a desirable feature of PTFE, the lack of fibrous ingrowth makes the repair more reliant on the inherent tensile strength of the material and the integrity of the suture attachment of the prosthetic to the fascia. This requirement for a high tensile strength suggests that a PTFE patch of 2-mm thickness should be used for incisional hernia repair.²¹

Serious complications have been observed in a small percentage of patients in whom prosthetic material has been used for incisional hernia repair. These complications include infection with or without chronic draining sinuses, erosion into adjacent structures including the intestine, and extrusion of the material.^{2, 24, 30} Voyles et al³⁰ have reported their long-term results with the use of Marlex mesh in 31 patients, 29 of whom had heavy contamination at the time of operation. The mesh was retained in only 18 of these patients, and 4 (22%) subsequently developed enteric fistulae while 14 (78%) ultimately extruded the mesh. Those authors advocated the removal of the mesh when possible if placed in a heavily contaminated field. These serious complications appear to occur much less frequently in the absence of contamination.² Recent clinical experience suggests that a wound infection after mesh repair typically does not mandate removal of the mesh in order to achieve resolution.^{2, 24} In an animal study comparing Marlex with PTFE, Brown et al⁴ demonstrated that Marlex was more susceptible to seeding with staphylococci than was PTFE, although there was no difference between the two in the frequency of polyorganism contamination.

Mesh Techniques

Onlay techniques (Fig. 5A) are rarely needed and can be dangerous if grafts are placed once the fascia has been closed. If the fascia can be brought together primarily, mesh does little to relieve any tension on the sutured repair.

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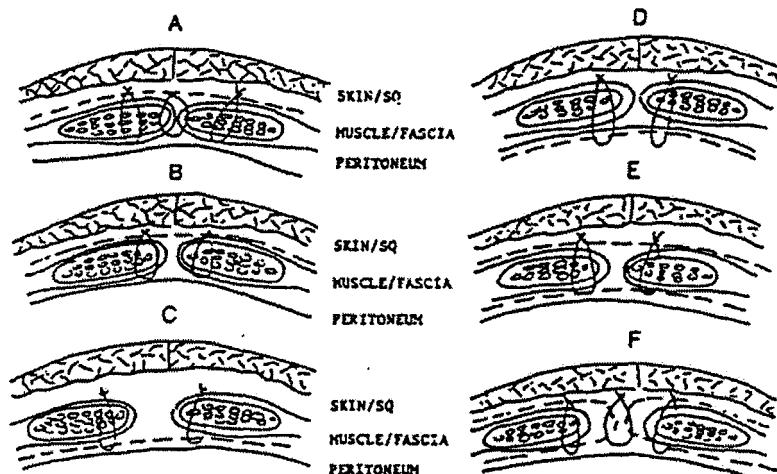


Figure 5. Anatomic options for prosthetic hernia repairs. *A*, Onlay, the mesh is placed in extrafascial space after fascia is approximated with suture. *B*, Extrafascial. *C*, Subfascial. *D*, Intraperitoneal. *E*, "Sandwich" technique—the deep mesh can be placed in the subfascial (as depicted) or in the intraperitoneal plane. *F*, "Cuff" technique—the mesh is wrapped around the margins of the defect on either side of the wound. The mesh-reinforced margins of the defect are then approximated. (---- denotes the prosthetic material.)

An onlay technique has been described that should avoid a bowel injury. The mesh is sutured to all layers of the fascia on one side under direct vision, and full-thickness sutures are then placed on the contralateral side and retracted prior to primary suture repair. After the suture repair and primary closure, the retracted sutures are used to secure the mesh over this repair.

Mesh can be placed in the extrafascial, subfascial, or intraperitoneal positions and can be used to support either side of the wound or both surfaces of the fascia (Fig. 5*B*, *C*, *D*, *E*, and *F*). Each technique has its supporters.

A number of specific technical points have been described that enhance the likelihood of a successful repair. These include a generous 4- to 8-cm overlapping of the mesh onto the fascia and secure suturing of the prosthetic to the fascia. Failure to adhere to these points has been cited as a cause of recurrence after mesh repairs.^{21, 22}

Recurrence

A recurrence after repair of an incisional hernia is obviously worrisome and a cause of great concern for all surgeons. Reported rates in the literature are typically in the 30% to 50% range.^{11, 22} By utilizing the technique of internal retention sutures, Sitzmann and coworkers²³ indicated that this rate can be reduced to 2.5%. The recurrence rates associated with the use of mesh have been reported to be approximately 10%. Typically, recurrences will be small, the result of a limited area of disruption between the mesh and the fascia, and simple repair can be undertaken for this local area. When mesh failures occur, they are frequently secondary to faulty implantation rather than material failure.

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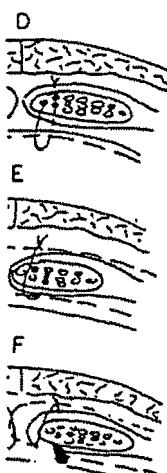
SPECIAL INCISIONAL HERNIAS

Massive Hernia

Patients with massive incisional hernias present with a functional loss of a large portion of their abdominal wall causing protrusion of a substantial portion of the abdominal viscera. Frequently, such hernias are associated with chronic abdominal pain, chronic back pain, and erosion of the overlying skin (Fig. 6). If the abdominal contents persist in the hernia sac, loss of abdominal domain may occur. Stoppa has outlined how loss of domain can lead to diaphragmatic dysfunction and intestinal circulatory congestion.⁴

The technique of introducing a pneumoperitoneum preoperatively to regain abdominal domain was reported in 1947. In more recent years, this technique has rarely been used because of the frequent use of tension-free mesh repairs. Nonetheless, a number of authors still contend that selected patients will benefit from progressive pneumoperitoneum, regardless of the repair utilized.⁵⁻⁸

Appropriate preparation for operation is mandatory in patients with massive incisional hernias. In order to reduce the risk of subsequent infection, all skin erosions should be resolved prior to elective repair. Moreover, pulmonary function should be optimized. It is our preference in such patients to utilize a tension-free repair, with prosthetic material being placed in either the intraperitoneal or the extrafascial position. Wide drainage should be utilized in order to eliminate dead space and fluid accumulation.



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tissue. C. Subfascial.
d. In the subfascial
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Figure 6. Massive incisional hernia. This patient has undergone many failed attempts at repair. This hernia arose as a complication of an abdominal gunshot wound in the remote past. A, Frontal view; inset shows close-up of skin erosion from the massive hernial process. B, Lateral view.

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Parastomal Hernia

Patients with a parastomal hernia usually present with a bulge and some discomfort at the area of their stoma. Moreover, this lesion typically results in difficulty securing the ostomy appliance to the skin. Parastomal hernia is believed to be a more common complication with a colostomy than an ileostomy.²⁴ Construction of an ostomy lateral to the rectus sheath results in a significant increase in hernia formation. Because of the likelihood of recurrence after repair of parastomal hernias,²⁵ a number of authors have begun to utilize mesh or relocation of the stoma to a new site.¹

Incisional Hernia with Enterocutaneous Fistula

Enterocutaneous fistulae are frequently associated with significant abdominal wall defects and large hernias. These problems provide a significant challenge for even the experienced clinician. Management should be directed at control of the fistula, after which consideration is given to the ultimate and definitive abdominal wall repair. Once the fistula has been resolved or controlled, the abdominal wall can be reconstructed with standard techniques. Use of mesh and a myocutaneous flap has been advocated by a number of authors in this setting.²⁶⁻²⁹

SUMMARY

Incisional hernias are a relatively common occurrence after abdominal operations, having been reported to occur in 2% to 11% of all patients undergoing such procedures. Although many hernias become manifest early, others may not be noted until many years after the index procedure. Predisposing factors for incisional hernia have been well described, and several of these can be altered by the surgeon, including the technique employed for repair. For many years, the repair of incisional hernia was associated with a high recurrence rate. In more recent years, the introduction of synthetic prosthetic materials has provided the opportunity to perform a tension-free repair, thereby reducing the rate of recurrence.

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resent with a bulge and some this lesion typically results in e skin. Parastomal hernia is th a colostomy than an ileos- ne rectus sheath results in a of the likelihood of recurrence authors have begun to utilize

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VII.2. T R E A T M E N T O F H E R N I A

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9 - Transperitoneal technique of preperitoneal mesh implantation in laparoscopic hernioplasty of direct and indirect inguinal hernias

CT. GERMER, D. ALBRECHT, C. BUTZ, J. SPRODER, A. WONDZINSKI, R. HARING,
Zentralblatt fur Chirurgie. 119 (4): 214-9 , 1994

07048

<14>
Unique Identifier
93236219
Authors
Sailors DM, Layman TS, Burns RP, Chandler KE, Russell WL.
Institution
Department of Surgery, University of Tennessee College of Medicine,
Erlanger Medical Center, Chattanooga 37403.
Title
Laparoscopic hernia repair: a preliminary report.
Source
American Surgeon. 59(2):85-9, 1993 Feb.
MeSH Subject Headings
Female
Follow-Up Studies
*Hernia, Inguinal/su [Surgery]
Human
*Laparoscopy
Male
Middle Age
Pain, Postoperative/ep [Epidemiology]
Polypropylenes
Postoperative Complications/ep [Epidemiology]
Surgical Mesh
Time Factors
Abstract
Advances in laparoscopic technique have provided the opportunity to perform preperitoneal herniorrhaphy and potentially avoid the morbidity associated with open techniques. From January 1991 to May 1992, two primary surgeons repaired 63 inguinal hernias (42 indirect, 20 direct, 1 femoral) on 48 patients using a standardized laparoscopic technique. The hernia defect was visualized laparoscopically, and the peritoneum anterior to the defect was incised. The hernia sac was dissected from the inguinal canal. The hernia defect was then loosely packed with rolled 1 x 6-inch polypropylene mesh (average number of rolls used was 3.4). A sheet of polypropylene mesh (average 5 x 8 cm) was then placed over the mesh rolls and the hernia defect and anchored with an endostapler. The peritoneum was closed over the mesh sheet with standard laparoscopic clips. There were 44 males and 4 females in the study group. The mean age was 55 years (range, 17-89 years). The mean follow-up was 5.8 months (range, 1-12 months). Thirty-three patients underwent unilateral hernia repair, and 15 patients underwent bilateral hernia repair. Clinically unsuspected contralateral hernias were identified at the time of laparoscopy in seven patients. The mean duration of surgery was 118 minutes (range, 80-165 minutes) for bilateral hernia repair, and 70 minutes (range, 45-100 minutes) for unilateral hernia repair. All patients with laparoscopic hernia repairs were treated on a same-day or less-than-24-hour in-hospital stay. Complications were designated as minor, moderate, or severe. There were 14 minor complications, which included subcutaneous hematomas at the trocar site, scrotal ecchymosis, groin swelling, emphysema, and testicular asymmetry. (ABSTRACT TRUNCATED AT 250 WORDS)
Registry Numbers
0 (Polypropylenes).

07049

<12>
Unique Identifier
93245579
Authors
Kunz R. Schutze F. Beger HG.
Institution
Abteilung fur Allgemeine Chirurgie, Universitat Ulm.
Title
[Laparoscopic herniorrhaphy of inguinal hernia. Reinforcement of the transverse fascia with surgical mesh]. [German]
Original Title
Laparoskopischer Bruchpfortenverschluss der Leistenhernie. Verstärkung der Fascia transversalis mit Netz.
Source
Chirurg. 64(4):341-5, 1993 Apr.
MeSH Subject Headings
Adult
Aged
English Abstract
Fascia/su [Surgery]
Female
*Hernia, Inguinal/su [Surgery]
Human
*Laparoscopy/is [Instrumentation]
Male
Middle Age
*Polypropylenes
*Postoperative Complications/su [Surgery]
Recurrence
Reoperation
*Surgical Mesh
Abstract
A basic principle of inguinal herniorrhaphy is the reconstruction of the transverse fascia. This laparoscopic technique described, consists in an augmentation of the transverse fascia by nonabsorbable mesh in pre-peritoneal position. Some aspects should be recommended for laparoscopic herniorrhaphy: The anatomic structures must be dissected exactly. The prosthetic mesh should be fixed to the fascia by multiple staples. With indirect inguinal hernias the mesh should encircle the spermatic cord.
Registry Numbers
0 (Polypropylenes).

07050

<9>

Unique Identifier

94119451

Authors

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Divisione di Chirurgia Generale, Ospedale Evangelico Internazionale,
Genova.

Title

[Recurrent inguinal hernia. The surgical procedure and technic]. [Italian]

Original Title

L'ernia inguinale recidiva. Tattica e tecnica chirurgica.

Source

Minerva Chirurgica. 48(17):943-5, 1993 Sep 15.

MeSH Subject Headings

Aged

English Abstract

Follow-Up Studies

Hernia, Inguinal/ep [Epidemiology]

*Hernia, Inguinal/su [Surgery]

Human

Italy/ep [Epidemiology]

Male

Middle Age

Polyethylenes

Polypropylenes

Recurrence

Surgical Mesh

Abstract

The authors describe two years and six months of personal experience in the treatment of recurrent inguinal hernia with polypropylene mesh. There was a follow-up with controls every 6 months with excellent results. From the data of the operation we programmed a further control 1'after 5 and 10 years. Considering the limited number of cases and the fact that the follow-up is not yet at completion, the information is provided as preliminary.

Registry Numbers

0 (Polyethylenes). 0 (Polypropylenes). 9002-88-4 (plastipore).

07051

</>

Unique Identifier

94326264

Authors

Katkouda N. Mouiel J.

Institution

Department of Surgery, University of Nice School of Medicine, France.

Title

Laparoscopic treatment of inguinal hernias. A personal approach.

Source

Endoscopic Surgery & Allied Technologies. 1(4):193-7, 1993 Aug.

MeSH Subject Headings

Follow-Up Studies

Hernia, Inguinal/cl [Classification]

Hernia, Inguinal/pa [Pathology]

*Hernia, Inguinal/su [Surgery]

Human

Iliac Artery/pa [Pathology]

Length of Stay

Ligaments/pa [Pathology]

Peritoneum/su [Surgery]

Polypropylenes

Psoas Muscles/ir [Innervation]

Recurrence

Stomach/b5 [Blood Supply]

Surgery, Laparoscopic/ae [Adverse Effects]

Surgery, Laparoscopic/is [Instrumentation]

Surgery, Laparoscopic/mt [Methods]

*Surgery, Laparoscopic

Surgical Mesh

Surgical Staplers

Umbilical Arteries/pa [Pathology]

Abstract

Laparoscopic hernia repair has suffered from a lack of careful anatomical appreciation and the application of sound surgical principles. Key anatomical landmarks which must be clearly identified in every hernia repair are Cooper's ligament, the umbilical artery and the epigastric vessels. The preperitoneal transabdominal mesh repair is the technique advocated by the authors. Between January 1991 and February 1993, 180 hernias were repaired. One hernia has recurred. Morbidity was minimal, with no major complication. The hospital stay was 1.3 days and the majority of patients returned rapidly to full activity. The best indications for laparoscopic hernia repair are recurrent hernias, a large hernia in patients with a weak muscular abdominal wall and bilateral hernias, for which the technique is considered ideal.

Registry Numbers

0 (Polypropylenes).

07052

Authors
Begin GF.
Institution
Clinique Sainte-Marthe, Dijon, France.
Title
Laparoscopic extraperitoneal treatment of inguinal hernias in adults. A series of 200 cases.
Source
Endoscopic Surgery & Allied Technologies. 1(4):204-6, 1993 Aug.
MeSH Subject Headings
Adult
Aged
Aged, 80 and over
Female
Follow-Up Studies
*Hernia, Inguinal/su [Surgery]
Human
Iliac Artery/su [Surgery]
Iliac Vein/su [Surgery]
Length of Stay
Ligaments/su [Surgery]
Male
Middle Age
Pain, Postoperative/ei [Etiology]
Peritoneum
Polypropylenes
Polytetrafluoroethylene
Psoas Muscles/su [Surgery]
Recurrence
Surgery, Laparoscopic/ae [Adverse Effects]
Surgery, Laparoscopic/is [Instrumentation]
Surgery, Laparoscopic/mt [Methods]
*Surgery, Laparoscopic
Surgical Mesh
Surgical Staplers
Abstract
Laparoscopic repair of 200 inguinal hernias by the preperitoneal approach is described. The technique uses a large mesh either of polypropylene or of ePTFE-Goretex. The average duration of the procedure was 45 minutes for unilateral hernias and 71 minutes for bilateral hernias. Postoperative pain was minimal and complications rare (no infection, one deep vein thrombosis). The mean duration of hospital stay was 44 hours. At a maximum follow-up of 22 months only one hernia has recurred. This technique of hernia repair has the advantage of minimal postoperative pain and early return to work with minimal recurrence of the hernia.
Registry Numbers
0 (Polypropylenes). 9002-84-0 (Polytetrafluoroethylene).

07053

<5>
Unique Identifier
94262334
Authors
Germer CT, Albrecht D, Butz C, Sproder J, Wondzinski A, Haring R.
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Title
[Transperitoneal technique of preperitoneal mesh implantation in laparoscopic hernioplasty of direct and indirect inguinal hernias].
[German]
Original Title
Die transperitoneale Technik der praperitonealen Netzimplantation zur laparoskopischen Hernioplastik direkter und indirekter Leistenhernien.
Source
Zentralblatt fur Chirurgie. 119(4):214-9, 1994.
MeSH Subject Headings
Adult
Aged
Aged, 80 and over
English Abstract
Female
Follow-Up Studies
*Hernia, Inguinal/su [Surgery]
Human
Male
Middle Age
*Polypropylenes
*Postoperative Complications/su [Surgery]
Prospective Studies
Recurrence
Reoperation
*Surgery, Laparoscopic
*Surgical Mesh
Suture Techniques
Abstract
The method of transperitoneal application of a large polypropylene-mesh in the preperitoneal space for laparoscopic inguinal hernia repair is described. The own experiences with a total number of 64 inguinal hernias are presented. The technique takes the principle of conventional hernia repair into account and appears to be a safe and effective way to repair indirect and direct inguinal uni- or bilateral hernias. During a mean follow-up of 24 weeks one recurrence occurred resulting from an inadequate application of the mesh. The technique presented is effective for laparoscopic inguinal hernia repair with low morbidity. Long-term follow-up is needed to determine late recurrence rate.
Registry Numbers
0 (Polypropylenes).

07054

<2>

Unique Identifier
95128739

Authors

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Institution

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Title

Early results of laparoscopic intraperitoneal onlay mesh repair for inguinal hernia.

Source

British Journal of Surgery. 81(12):1761-2, 1994 Dec.

MeSH Subject Headings

Adolescence

Adult

Aged

Aged, 80 and over

Female

*Hernia, Inguinal/su [Surgery]

Human

Length of Stay

Male

Middle Age

*Polypropylenes

Surgery, Elective

*Surgery, Laparoscopic/mt [Methods]

*Surgical Mesh

Abstract

Over a 15-month period, 39 patients (37 men) of mean age 52 years underwent laparoscopic inguinal hernia repair. Seven patients had bilateral hernia. Forty-six hernias (33 indirect, five direct, eight both direct and indirect) were repaired. A piece of polypropylene mesh measuring 8 x 10 cm was used to cover the direct and indirect spaces with an endoscopic multifeed hernia stapler. The mean operating time for unilateral and bilateral repair was 49 and 63 min respectively (range 25-90 min). One-third of patients required no postoperative analgesia and only seven had more than one injection of pethidine. The median postoperative stay was 1 (range 1-3) days. The mean period to resumption of daily activities was 7 (range 4-21) days. Three patients complained of paraesthesia of the lateral aspect of the thigh and one developed a hydrocele. Two recurrences were noted on follow-up at 3 months.

Registry Numbers

0 (Polypropylenes).

CONFIDENTIAL

SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

ETH.MESH.06398907

07055

<1>
Unique Identifier
93355378
Authors
Himpens JM.
Institution
Department of General Surgery, Algemene Kliniek H. Familie, Gent, Belgium.
→ Title
Laparoscopic inguinal hernioplasty. Repair with a conventional vs a new self-expandable mesh [see comments].
Source
Surgical Endoscopy. 7(4):315-8, 1993 Jul-Aug.
MeSH Subject Headings
Alloys
Comparative Study
Female
*Hernia, Inguinal/su [Surgery]
Human
*Implants, Artificial
Male
Polyethylene Terephthalates
Polypropylenes
Postoperative Complications/ep [Epidemiology]
Prospective Studies
Recurrence
*Surgery, Laparoscopic
*Surgical Mesh
Surgical Staplers
Time Factors
Abstract
Laparoscopic hernioplasty was performed in a prospective fashion in 100 inguinal hernias in 66 patients. When available, a self-expanding prosthesis of Mersilene, strengthened with a cross- or star-shaped wire of Nitinol, was used without fixation (group B, 43 hernias). When this prosthesis was not available, a "classic" Prolene prosthesis was used, placed preperitoneally, and stapled according to the technique of Corbitt (group A, 57 hernias). This study compares the results of the two techniques. The use of a mesh-expanding Nitinol frame significantly shortens the operating time. Since two recurrences appeared in this group, we suggest that this modified mesh should also be stapled in place.
Registry Numbers
0 (Alloys). 0 (Polyethylene Terephthalates). 0 (Polypropylenes).
25038-59-9 (Lavsan). 52013-44-2 (nitinol).

REPAIR OF INGUINAL HERNIA IN THE ADULT WITH PROLENE® MESH

07056

Joseph A. Capozzi, M.D., F.A.C.S., J. Alan Berkenfield, M.D., and
John K. Cherry, M.D., F.A.C.S., La Jolla, California

Three surgeons in the private practice of general surgery began to use Prolene® (polypropylene) mesh in the treatment of all adult inguinal hernias in 1978. The reason for using this technique was to perform a truly tension-free repair to reduce the recurrence rate and produce less pain and disability postoperatively. The rational for using Prolene as the mesh material is discussed in relation with the other materials available. The technique is outlined in detail along with precautions to decrease the already low recurrence rate documented in this series.

From 1978 through 1985, 745 repairs were analyzed. The complication and recurrence rates were minimal, and the follow-up rate was 87 per cent. A plea is made not to report recurrence rates without follow-up rates. This technique is simple and effective and should be seriously considered in the treatment of hernias occurring in adults.

THE RECENT EXPERIENCES of three surgeons in the private practice of general surgery at one hospital in the surgical treatment of inguinal hernias occurring in adults is presented herein. All of the hernias were repaired with Prolene® (polypropylene) mesh whether they were initial or recurrent. This technique was used in the repair of hernias of the abdominal wall as well; however, our study will concern itself with inguinal hernias. The mesh was used in all instances of inguinal hernias except in the pediatric patient or young adult with an obvious congenital indirect sac and no weakness of the abdominal wall. The reasons for using the mesh are quite simple. When the mesh is sutured into tension-free tissues, there is less postoperative pain and disability. The recurrence rate should be less than conventional repairs because of less tension and because of the fibroblastic proliferation produced by the mesh in the inguinal floor. This study was conducted from 1978 through 1985 and included 745 repairs.

PATIENTS AND METHODS

Between 1978 and 1985, we performed a Prolene mesh repair 745 times upon 579 patients. We contacted 651 patients after repairs with an average follow-up period of 5.06 years (Fig. 1).

There were 745 herniorrhaphies performed upon 579 patients (Fig. 2). Of these patients, 542 were men and 37, women. The hernias were direct in 337, indirect in 281 and combined in 127. Sixty were sliding, 22 were incarcerated and 84 were recurrent. Ninety-four patients were lost to follow-up study, leaving 651 repairs for analysis.

OPERATIVE TECHNIQUES

Basically, exposure is obtained by splitting the external oblique fascia in the direction of its fibers through the external inguinal ring. The spermatic cord or round ligament is then elevated out of the inguinal canal. An indirect inguinal hernial sac is then searched for and, if present, is entered, and internal palpation is done to document the presence or absence of femoral or direct hernial defects, or both. The sac is then ligated with both a pursestring suture and another suture high in the neck, and the excess sac is removed. If there is no indirect sac, the transversalis fascia is minimally opened to search for a femoral hernia. If a femoral hernia is encountered, it is reduced. The mesh can be made to cover this defect by simply cutting a flap into it and sewing this down to Cooper's ligament or by inserting a separate rolled-up plug of Prolene mesh about 2 centimeters long, which is wide enough to insert into the femoral canal to occlude the space and not compromise the femoral vessels, and secured by three 2-0 Prolene sutures—one medially, laterally and superiorly. If the plug is used, the mesh can then be sutured in place in the usual manner. Direct hernial defects are controlled by loosely imbricating the attenuated transversalis fascia where it is redundant. The round ligament is usually sacrificed in women, but can be left intact, if desired. The ilioinguinal nerve is usually left intact.

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07057

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on the anterior surface of the spermatic cord or round ligament, or retracted medially or laterally out of the way. A suture is then used to incise at the distance from the pubic tubercle laterally and superiorly along the shelving edge of the inguinal ligament to a point some 3 to 4 centimeters lateral and superior to the internal inguinal ring (Fig. 2, A to C). The distance from the inguinal ligament medially to strong internal oblique fascia or rectus sheath, or both, provides the other dimension of the mesh prosthesis (Fig. 2, D to E). At our hospital, the mesh is pre-cut and packaged sterile in 8 by 10 centimeter sheets to reduce the cost to the patient to \$39.50. The mesh prosthesis is usually rectangular in shape with a medial and inferior end trimmed into an ovoid configuration to conform to the curve of the internal oblique and transversalis fascia as they converge upon the pubic tubercle. A keyhole is made to permit egress of the spermatic cord or round ligament (Fig. 3) at the internal inguinal ring, usually conveniently measured from the pubic tubercle to the inferior surface of the spermatic cord (Fig. 2, A to B) or round ligament as it exits beneath the internal oblique muscle and about 1 centimeter medial to the inguinal ligament. If the spermatic cord or round ligament has been sacrificed, no keyhole is needed. Care is taken not to include the nerves in suturing the mesh in place with a continuous 2-0 Prolene suture. Another suture is needed to close the slit part of the keyhole. This is a very important suture (Figs. 4 and 5). The mesh can be made to fit any configuration in the inguinal area but should be large enough to be at least 2 centimeters above the spermatic cord or round ligament. The most dangerous time to suture the nerve is while closing the slit of the keyhole. The spermatic cord or round ligament is then laid down on the mesh and the nerves restored to the anatomic positions and the external oblique closed anterior to this with a continuous 4-0 absorbable suture. The subcutaneous and skin layers are closed individually by various techniques.

RESULTS

The poor results were classified as those being residual pain, removal of the mesh and recurrence. This number totaled eight patients in the poor result category. The remainder of the patients were extremely satisfied with the results. The number of repairs lost to follow-up study was 94.

Seven patients in this series had a subcutaneous wound infection, which, in two instances, went

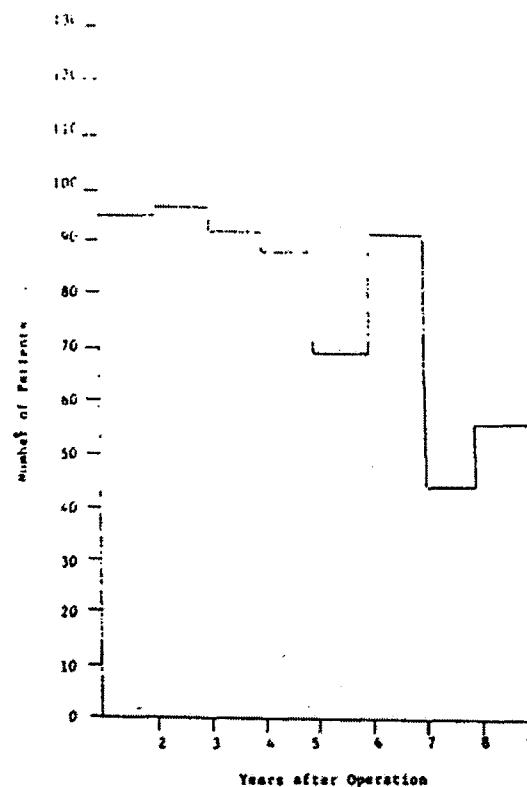


FIG. 1. Diagram of average follow-up study of 5.06 years.

down to the mesh layer. None of these needed removal of the mesh and all healed with simple drainage and packing and other conservative measures. No prophylactic antibiotics were used unless the hernia operation was done in conjunction with another procedure. Four patients had seromas develop, which resolved with simple aspiration. Postoperative pain caused by nerve entrapment was a fleeting problem in several patients and is residual in one patient. A few patients needed nerve blocks for relief of pain in this area; almost all subsided spontaneously. Three patients had the mesh removed for either discomfort or psychologic reasons. Four patients had recurrences of whom one patient underwent reoperation. The recurrence was found to be at the internal inguinal ring where the opening in the mesh was not closed. The other three have decided not to undergo an operation at this time. One of these recurrences is thought to be femoral; one medial and one superior to the insertion of the mesh. The importance of closing the keyhole slit and making the mesh large enough cannot be over-emphasized: it could have eliminated these recurrences. Postoperative disability has been reduced greatly with this technique.

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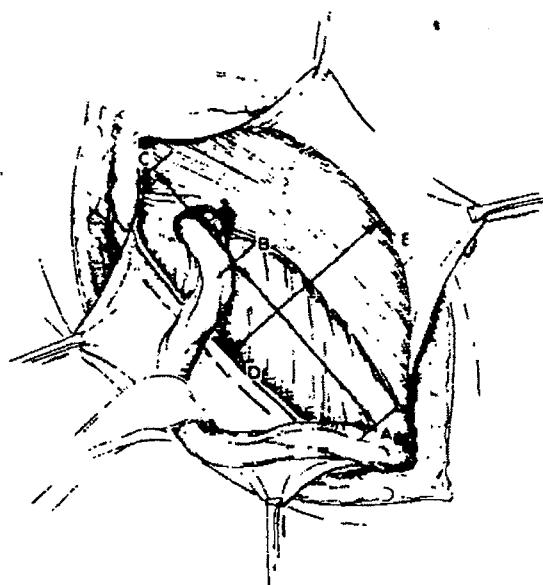


FIG. 2. Diagram of inguinal floor showing measurement dimensions. *A* to *C*, *D* to *E* and *A* to *B*

DISCUSSION

The technique of using mesh in hernial repair is not new, but surgeons have been reluctant to use mesh in a hernia unless it was a recurrent one. The teaching was that mesh is a foreign body and should not be used unless the tissues were too weak to maintain their integrity. This was based upon the mesh materials available at that time, which had basic problems. The tantalum wire mesh could break and splinter, producing areas of weakness and pain. Mersilene® (polyester fiber) has a tendency toward infection and foreign body granulation. Marlex® (polypropylene) and Prolene are both monofilament polypropylene and have been shown to be resistant to infection. Prolene molds itself to the body creases because of the method of doubled knitting, which interlinks each junction to produce bidirectional elastic properties.

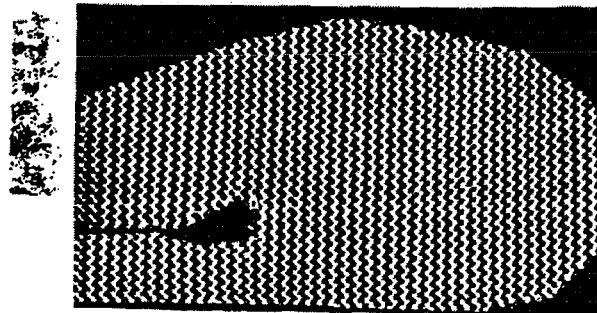


FIG. 3. Prolene® (polypropylene) cut mesh with keyhole.

It can be trimmed to any configuration without unraveling. It is very strong, able to stand 250 pounds of pressure per square inch. A dense fibrous reaction takes place around and through the mesh, and this, in addition, strengthens the inguinal floor.

The idea was entertained that using mesh in the patients with direct hernias would reduce the tension on the tissues and, therefore, decrease postoperative pain and disability as well as reduce the recurrence rate because of the decreased tension and stronger inguinal floor. Using the mesh in adult patients with indirect hernias and a relatively normal inguinal floor would be added insurance against developing a direct hernia later in life.

What are the disadvantages of using mesh on all adult patients with inguinal hernias? The first objection is that it is a foreign body and could be rejected. We have not found this to occur in more than 1,000 instances of hernias of the abdominal wall. Another objection is that, if infection occurred, it could possibly necessitate removal of the mesh and compromise the hernia repair. Again this was not borne out in this series, and others have reported the resistance to infection of the mesh. The only problem encountered in this series in using the mesh was one of incorporating the ilioinguinal or iliohypogastric nerves, or both, in suturing the mesh in place. This can result in pain postoperatively, which readily responds to a few nerve blocks until the reaction subsides, usually about six weeks. This complication can be avoided by attention to detail while suturing the mesh.

Some patients cannot psychologically adapt themselves to the idea that a foreign body is being inserted into their bodies. These patients are usually screened out by informed consent during the preoperative office visit.

Most patients undergo treatment as outpatients. These patients are told to perform any physical activities they wish to within the realm of their discomfort. They are also told that "if it hurts, don't do it or do it very carefully and gently." This may last up to seven days, but is usually less. Since the mesh is sutured in place anatomically with no tension by pulling tissues together, the postoperative discomfort is markedly decreased. The only limitation put on the patients is that they are not to drive a car until they believe that they can move their leg quickly enough and with adequate force to produce a panic stop in traffic to avoid an accident. They are usually back to work within the week, with some

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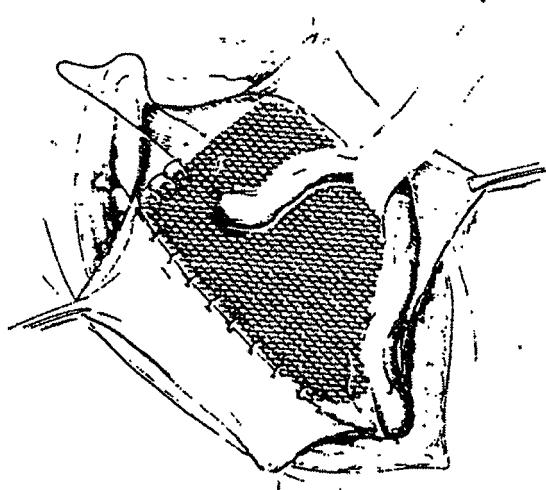


FIG. 4

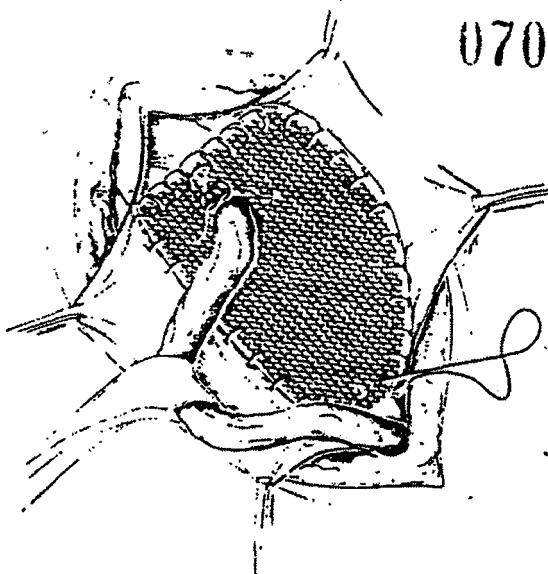


FIG. 5

Fig. 4. Suturing the mesh into place
Fig. 5. Completion of suturing of mesh

individuals returning to sedentary jobs within three days. Bilateral hernias are performed at the same time.

We removed the mesh in one patient because of pain. (This patient required psychiatric care and eventually had an orchiectomy performed by another physician.) The mesh was removed four months postoperatively and histologic examina-

tion revealed the marked fibrotic reaction seen in Figures 6 and 7. The gross specimen was quite impressive because of the strength of the fibrotic reaction. The strength of the mesh added to the fibroblastic proliferation that occurs within the mesh produces a very strong inguinal floor. Prolene mesh was used because of its strength, ability to withstand infection, immediate fibroblastic



FIG. 6

Fig. 6. Lumens represent areas where the mesh filaments were removed. Areas between reveal the fibroblastic reaction. Hematoxylin and eosin, X200.

Fig. 7. Histiocytes lining the lumen that held the Prolene® (polypropylene) strand with fibroblastic reaction around it. Hematoxylin and eosin, X200.

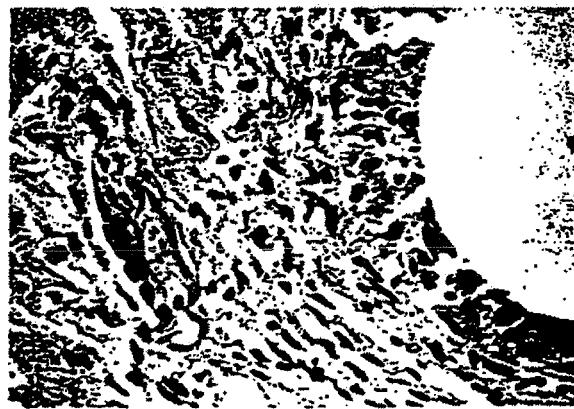


FIG. 7

07060

128 *Surgery Gynecology & Obstetrics*, August 1985, Volume 160

reaction and easy handling characteristics. Met-silene is braided Dacron^{*} (polyester fiber) and is subjected to infection. Marlex seems stiffer than Prolene and does not handle with the same flexibility. Gore-tex^{*} (reinforced polytetrafluoroethylene) does not produce enough of a reaction initially to hold it in place and must rely totally on the sutures to keep it secure. The area superior to the cord that the mesh is secured to is internal oblique muscle. The muscle has little holding quality and suturing with Gore-tex could easily pull out and result in a recurrence. Prolene causes enough of an initial reaction to hold it in place until the stronger fibroblasts secure it permanently. The thought at this time is that Prolene is the most ideal mesh prosthetic for this situation.

SUMMARY

This technique should be adopted by more surgeons in the treatment of the repair of inguinal

hernias in adult patients. The caveats in using this technique are 1, do not use mesh in a teenager who has a strong inguinal floor or in a patient who does not want the mesh, 2, make certain the mesh is large enough to go well above the internal inguinal ring and over to good fascia medially, 3, close the keyhole slit, 4, avoid incorporating nerves in suturing the mesh in place, and 5, examine the femoral canal carefully. The advantages to this technique are that it is easy to perform technically, can be done on an outpatient basis using local anesthesia, if desired, causes less pain and disability than other methods, and has a recurrence rate less than other methods if performed correctly.

REFERENCES

- KALFMAN, M., WEISSBERG, D., and BIDER, D. Repair of recurrent inguinal hernia with Marlex mesh. *Surg. Gynecol. Obstet.*, 1985, 160 505-506

VIII. RISK ANALYSIS

ETHNOR SA - PROLENE® Mesh Technical File - BP - July 1995 Section 8 Page 2

PROLENE® Mesh was put on the US market in 1973. At that time, the regulations did not require risk analysis as described in EEC Directive 93/42 relating to medical devices.

The table summarizing the risk analysis related to the use of PROLENE® Mesh has since been drawn up. The study of the characteristics identified as possibly presenting a risk to the patient shows that this risk is acceptable considering the benefit brought by the use of these devices.

1992

11717 units sold by France => 2 complaints registered and confirmed by the laboratories for the reason "cover imprinting error."

1993

13872 units sold by France => 1 complaint registered and confirmed by the laboratories for the reason "product does not correspond to stated dimensions." 6 complaints are registered but none was confirmed after investigation.

1994

14481 units sold by France => 2 complaints are registered and confirmed by the laboratories for the reasons "absence of product in blister" and "empty pack."

None of the complaints registered call into question the sterility of the products nor biological problems (suppuration, abscess, etc.).
The ratio of complaints/number of units sold is very low. The level of complaints registered by the laboratory over the last three years of sale in France permits the conclusion that the use of PROLENE® Mesh does not call into question the safety of the patient.

CONFIDENTIAL SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

ETH.MESH.06398916

ETHNOR S.A. - Technical File on PROLENE® Mesh - BP - July 1995

Section 8 Page 3

ref EN 1441	Characteristics 4.2	Danger 4.3	Risk for Patient 4.4	Frequency 4.4	Acceptance 4.5	Modification 4.6	Other Danger 4.7	Final Acceptance 4.8
4.2-a	<u>Users:</u> -Surgeon -Dressings nurse -Instrument <u>Environment</u> Operating block	Lack of asepsis: -Poor delivery -Cutting of gloves by wrapping	Critical risk Critical risk	Low Low	No No	Personl. training User instructions Personl. training	No No	Yes Yes
4.2-b	<u>Contact:</u> -Total implantation <u>Contact time:</u> -Long term <u>Invasive contact:</u> -Yes <u>Frequency</u> -Associated w/numbers & type of surgical operations	Biological incompatibility Risk of sepsis	Allergy, extrusion Critical risk	Very low Very low	Yes Yes	Biocompatibility tests review Sterility level: 10^{-6}	No No	Yes Yes
4.2-c	Mesh: propylene thread	Biological incompatibility	Extrusion	Very low	Yes	Biocompatibility History	No	Yes
		Cutting error defective appearance, damaged mesh, resistance to bursting too low Presence of foreign substances	Incorrect performance Product unusable	Low Low	No	NQA checks SM during manufacture	No	Yes
4.2-d	Not applicable							
4.2-e	Not applicable							
4.2-f	Not applicable							

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ref EN 1441	Characteristics 4.2	Danger 4.3	Risk for Patient 4.4	Frequency 4.4	Acceptance 4.5	Modification 4.6	Other Danger 4.7	Final Acceptance 4.8
4.2-g	Sterile device Simple use	Non sterility-risk of sepsis	Critical risk	Low	No	Validation acc. to EN556 (sterility level 10 ⁻⁶) Instructions for use	No	Yes
	<u>Wrapping:</u>	Incomplete sealing, perforated or damaged blister, absence of lacquer on Tyvek®, presence of foreign substances. Sealing width inadeq., blister damaged without perforation Foreign substances: secondary pack	Non-maintenance of sterility Critical risk Moderate risk Low risk	Low Low Low	No	NQA checks SM during manufacture	No	Yes
	<u>Maintenance of sterility</u> -5 years <u>Sterilization proc.</u> -ethylene oxide	Device not sterile, degradation of performance Non-sterility, modification of performance	Critical risk Critical risk	Very low Very low	No	Verification of stability, incl. sterility Validation acc. to Std. EN550 Validation of Finished Prod.	No No	Yes Yes
4.2-h	Not applicable							
4.2-i	Not applicable							
4.2-j	Not applicable							
4.2-k	Not applicable							
4.2-l	Not applicable							

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ref EN 1441	Characteristics 4.2	Danger 4.3	Risk for Patient 4.4	Frequency 4.4	Acceptance 4.5	Modification 4.6	Other Danger 4.7	Final Acceptance 4.8
4.2-m	<u>Environmental influence</u> -Storage -Transport -Storage client	Loss of integrity of wrapping Loss of sterility Loss of performance of device	Risk of sepsis Incorrect performance	Low	No	-Review of prod. -Test products stored 20 yrs. -Storage recom. given in User Instruction	No	Yes
4.2-n	Not applicable							
4.2-o	Not applicable							
4.2-p	Non applicable							
4.2-q	<u>Expiration date:</u> -5 years -Date of expiration shown on labelling	Information missing, incorrect or illegible	Performance of product	Low	No	NQA checks during manufacture	No	Yes
4.2-r	<u>Delayed effects:</u> -Loss of strength <u>Long-term effects:</u> -No known cumulative effect	Mesh no longer functions, dehiscence of wound	Risk is low, known and indicated under "Performance of Device" (User Instruction)	Very low	Yes	No	No	Yes

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